

The Role of Design in Home-Based Health-Care Equipment

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A thesis submitted in partial fulfillment of the requirements of
De Montfort University for the degree of
Doctor of Philosophy



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January 2000

Author Declaration

1. During the period of registered study during which this dissertation was prepared the author has not been registered for any other academic award or qualification.
2. The material included in this dissertation has not been submitted wholly or in part for any academic award or qualification other than that for which it is now submitted.

Sang-Young Lee

November, 1999

Dedication

Glory be to the Father, the Son
and the Holy Spirit;
as it was in the beginning is now
and ever shall be.

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a PhD thesis by
Sang-Young Lee

Abstract

This thesis describes a study of the role of design in the home-based health-care (HBHC) industry. The research included a hospital user survey, a manufacturer survey and 3 case studies.

The hospital user survey was conducted in four hospitals and a total of 133 patients and 13 staff at five units was involved. The manufacturer survey involved 22 manufacturers; 22 questionnaires were received and 32 people co-operated with interviews. The 3 case studies involved interviews, analysing company literature and looking at products.

The major findings from these studies are:

- 1) The home-based health-care market is growing with market demand and advances in technology, allowing development of new products for the HBHC market. Economic forces, namely, heavy financial pressure restricting hospital activities, are clearly behind the trend of movement of health care into the home.
- 2) A taxonomy of HBHC equipment could consist of 7 categories, - respiratory, hearing aids, hygiene & transferring, therapeutics, dialysis, monitoring and ambulatory drug delivery equipment.
- 3) The use of equipment at home offers many significant benefits to patients. These include convenience, saving time, saving travelling, safety, etc.
- 4) A particular problem in designing HBHC equipment or medical equipment is producing a product which properly accommodates the different needs of different users. From the users' point of view, some problems were identified relating to set-up, control and maintenance.
- 5) Some home-based health-care equipment could be redesigned with domestic use in mind. This could improve usability and decrease the time required for training.
- 6) The healthcare industry is very traditional, most of the equipment being designed by engineers within the companies involved. There are still misunderstandings about the role of industrial design. To many people in the industry, 'design' means 'engineering design' and not 'design for people'.
- 7) Regulatory matters have an important impact on design procedures. The result is a focus on the safety aspects of design and construction rather than the users' point of view.
- 8) All the companies claimed to have featured users' opinions in some way in their product change brief. It was claimed that customers' opinion is very important in order to develop a further direction for new product development. In reality, user opinions were found to have been largely ignored by companies. This was particularly true when users and customers (buyers) are different.

Acknowledgements

It is inevitable that a broadly based thesis such as this should rely on a wide range of influences. This research project has required guidance, co-operation and feedback from a number of individuals to produce the results that are presented in this thesis. I would like to thank those who have been involved with the project and those who have provided a good listening ear to the problems I have encountered along the way.

More specially, however, I would like to extend my deepest gratitude to my Director of Studies, Dr. John Langrish, for his valuable guidance, constructive criticism and encouragement from beginning to end. His mastery of inter-disciplinary research and open-mindedness have been essential for the successful completion of this work. I would also like to thank my second supervisor, Mr. Chris Greensides, for his valuable comments and advice on many aspects of the study. His suggestions and criticism on my first draft and the comments on the quality of the research are also gratefully acknowledged.

Thanks are also due to my advisor, Prof. Tom Cassidy, for his continuous help and support during my Leicester years. Especially, when I had insurmountable difficulties, losing my computers and suffering financial loss because of seven burglaries, his warm heart and encouragement motivated me to start my research again. I am also thankful to Mr. Ray Holland for his support and help to facilitate me to carry out my research. In addition, I would like to acknowledge Ms. Joanne Cooke of the Research Office, for her kind work and help for me.

This research would not have been possible without the full support of the individuals, companies, hospitals and other organisations who facilitated my understanding and knowledge of the home-based health-care industry and medical equipment industry. May I also express thanks to them all. Especially, I thank my dear friend, John Harding and his wife, Oonagh Rowe, who promoted my research both with Huntleigh Nesbit Evans Technology plc Group and the Dorset Healthcare NHS Trust.

I am indebted to the Foreign and Commonwealth Office Special Scholarship for the academic year 1998/99 and to Mark Attlee, Secretary of the Scholarship Board, for his concerns about my study and help. I should also like to thank Maria Bragoli for her reading and corrections of this thesis.

I wish to express my sincere thanks to all the people who prayed for me. In particular, I would like to especially thank my parents and two younger sisters, Joo-Yeon and Ji-Young, for their continual confidence in my ability to do this PhD, and for all the support they have given me during my 'research years in England'.

Finally, my special thanks go to my colleague and dear wife, Eun-Sook Shim, for her intellectual and practical support and prayer during the study.

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Abbreviations

2D	Two dimensional
3D	Three dimensional
ABHI	Association of British Healthcare Industry
AIDS	Acquired immune deficiency syndrome
APAM	Alternating pressure air mattress
APD	Automated peritoneal dialysis
ATM	Assistance Technique Medicate
BC	Before Christ
BD	Becton Dickinson
BM	Boehringer Mannheim
BQH	Birmingham Queen Elizabeth Hospital
CAD	Computer aided design
CAPD	Continuous ambulatory peritoneal dialysis
CAT	Computerised axial tomograph
CCPD	Continuous cycling peritoneal dialysis
CDRH	Centre for Devices and Radiological Health
CE	European Conformity
CPU	Central processing unit
CT	Computerised tomograph
D/S	Disposable syringes
DM	Deutsche mark (German currency)
ECG	Electrocardiography
EEG	Electroencephalography
EMG	Electromyography
EMS	Electro Medical Supplies
ESRD	End stage renal disease
FDA	Food and Drug Administration
FMEA	Failure Mode and Effects Analysis
GMP	Good Manufacturing Practice
GP	General Practitioner
HBHC	Home-based health-care
HD	Haemo dialysis
HD	Home diabetes
HDG	Haemo diafiltration
HF	Haemo filtration
HFA	Health for all
HHD	Home haemo dialysis
HIV	Human immunodeficient virus
HNE	Huntleigh Nesbit Evans
HosHD	Hospital haemo dialysis
HPD	Home peritoneal dialysis
HR	Home respiratory
Inc	Incorporated
ISO	International Organisation for Standardisation
IT	Intensive therapy

ITU	Intensive therapy unit
IV	Intravenous
J/V	Joint venture
LED	Light emitting diode
LGH	Leicester General Hospital
Ltd	Limited
M/N	Medix nebulizer
M/S	Monitoring system
MDA	The Medical Devices Agency
MDD	The Medical Devices Directive
MedGV	Medical Equipment Ordinance (Germany)
mg/dL	Milligram/ diffusing capacity of lungs
MRI	Magnetic resonance imaging
NHS	National Health Service
OCH	Oxford Churchill Hospital
OEM	Original equipment manufacturer
PCB	Printed circuit board
PD	Peritoneal dialysis
PFI	Private Funding Initiative
plc	Public Limited Company
PRG	Project Review Group
QSR	Quality System Regulations
R&D	Research and Development
R/O	Reverse Osmosis
RSA	The Royal Society for the Encouragement of Arts, Manufactures & Commerce
SDL	Specification and Description Language
SDT	SDL Design Tool
SEK	Swedish krona (Swedish currency)
TENS	Transcutaneous electric nerve stimulation
TPN	Total parenteral nutrition
TUV	Technical Inspection Associations (Germany)
UF	Ultra filtration
VAT	Value Added Tax
WHO	World Health Organisation

Chapter 1

Home-Based Health-Care Equipment

CHAPTER 1 HOME-BASED HEALTH-CARE EQUIPMENT

1.1 Introduction

The boundaries between home and public health-care are constantly shifting. Marks (1991) claims,

The perception that hospitals form the centrepiece of health-care systems is relatively recent. In nineteenth century Britain, those who could afford it were cared for at home; hospitals were largely populated by the sick poor. By the 1920s, this began to change and hospitals gained in popularity with the rich and newly emerged middle classes (p.5).

According to Stocking (1992) and Marks (1991 and 1992), hospital-based health-care continued to be dominated by biomedical advances, including effective treatments and improved anaesthetic techniques, the advent of high technology medicine and the necessity of rationalising specialised staff and expensive equipment. In recent years however, there have been new trends in health-care, with health-care moving into the home, and increasingly, health-care equipment has been designed for use at home.

The first chapter discusses home-based health-care (HBHC) equipment. This first section provides a historical review of health-care. It focuses on explaining why and how health-care has been developed and changed. Section 1.2 is concerned with the reasons behind the shift to home care. Section 1.3 discusses the definition and status of health-care and medical care. Section 1.4 describes home-based health-care. Section 1.5 explains the relationship between home-based health-care equipment and technology. Section 1.6 gives a definition and classification of home-based health-care equipment. The last section discusses design problems and needs in present home-based health-care equipment.

Promotion of health

Wherever people have congregated together in towns and cities the ensuing sanitary problems have stimulated a public health response. This broad area of public health represents, in a sense, a rediscovery of ancient concepts.

As long ago as 3000 BC, cities on the Indian subcontinent had developed environmental sanitation programs such as the provision of underground drains and public baths.

Essential aspects of health were woven into daily activities, including personal hygiene, health education, exercise, codes of conduct and self-discipline, dietary practices, food and environmental sanitation, and treatment of minor ailments and injuries. By 1400 BC, Indian society's so-called science of life, or Ayurveda, mainly featured total health-care through health promotion and education, although advances were also made in curative medicine and surgery (Rosen, 1958; Terris, 1994).

This tradition was also highly developed in ancient Greece and Rome and has persisted to the present day, but it has been overshadowed in the 20th century by the great advances in the prevention and treatment of disease. Only in recent decades has a resurgence of interest in positive health occurred. This is evidenced by the important research conducted on the effect of malnutrition in pregnant women on the physical and mental development of their children, and research on the effects of diet supplementation in improving the health and vitality of undernourished populations; by the studies of optimal levels of temperature and other environmental conditions affecting human comfort and ability to function; and by the widespread recognition of the value of physical exercise in achieving positive health and well-being (Ashton, 1994; Terris, 1994).

Disease prevention by public action

The Industrial Revolution produced both overcrowded, unhealthy conditions and local and national governments with the resources to tackle those conditions. Although many writers, e.g. Terris (1994) follow the tradition of basing improvements in health on advances in science, it seems more likely that improved practices came before improved scientific understanding. Langrish (1972) claims that improvements in the control of water supplies came before the arrival of germ theory. Similarly, practical and effective vaccination did not grow out of scientific understanding.

Environmental sanitation-safe water supplies, improved sewage disposal systems, pasteurisation of milk, and sanitary control of food supplies, resulted in the virtual disappearance of cholera and typhoid fever and the marked reduction in diarrhoea and infant mortality in industrial countries (Ashton, 1994; Terris, 1994).

The discovery of effective vaccines led not only to the recent world-wide eradication of smallpox but also to the marked decline in such diseases as diphtheria, tetanus, whooping cough, poliomyelitis, and measles (Hobson, 1979; Terris, 1994). Hobson (1979) claims that lack of adequate sanitation facilities, however, still impedes the developing countries in their efforts to reduce the toll of diarrhoea in infants and children-the main cause of death in the world today. Malaria, tuberculosis, influenza, and other infectious diseases also remain as major health problems in many countries.

In 19th century Europe and North America, the rapid growth of industrial towns created the conditions under which epidemic disease was rampant. Initially, governments were reluctant to introduce reforms and it was arguably the Health of Towns Commission in England which produced the momentum for change (Ashton, 1994).

The Health of Towns Commission had been set up by the Government in 1843, with Edwin Chadwick taking a lead role. It produced detailed reports on the poor conditions existing in many cities. The 50 most insanitary towns in England were described and there were special reports on Liverpool, Preston, Nottingham, Leicester, York and Huddersfield. These narratives shocked many people. They showed how desperate the plight was of so many people living huddled together in dark, damp cellars (Lewis, 1952).

According to Finer (1952) the report of the Commission in July 1844 gave the impetus for the Health of Towns Association to be set up later that year. Finer also describes how the document stressed that the water supply that was needed to scour the proposed drains and flush the sewers was supplied by private water companies at exorbitant prices in inadequate quantities. It focused on the need for plentiful, safe water and the idea of sanitation both of which were to become powerful motivating forces in town halls during the following decades.

Taylor (1989) claimed that in the early decades of Victoria's reign hospitals were widely seen as places for the poor or 'dangerously' sick (such as those with communicable diseases) who, because of some special misfortune, could not be cared for at home. But during the past century such institutions have become firmly established as the main

focus of medical, nursing and allied skills. Patients go to hospitals because there they expect to find and receive the best, most sophisticated care possible.

With their large specialist staff and complex technical facilities, concentrated 'on site', hospitals are obviously a vitally important element within any modern health service. Nevertheless, there is now growing attention being paid to the concept of caring for seriously ill people at home, offering them intensive domiciliary support for limited periods in order to avoid admission to hospital, or to keep their stay there as short as possible (Taylor, 1989).

1.2 Trends in home-based health-care

The home health-care industry has grown rapidly since about 1980. Cockerill (1992) estimates that the world market has more than doubled in the last six years. It is claimed (Williams et al., 1988) that in the USA, from 1978 to 1986, the number of hospital-based home health-care agencies more than doubled to over 1,000. During the same period, the number of independent home health-care agencies grew by over 80%. As regards Germany, Gerdemann (1992) states that in 1986, the health insurance funds spent 160.3 million DM (£ 55 million) on home care and in 1990, 1,046 million DM (£ 359 million). This is an increase of 553 per cent in only 4 years.

These growths are the result of the tremendous change occurring within the health-care industry. Pressures from insurers, employers, and governments to reduce health-care costs, advances in technology which include medical technology, and an increase in patients' sophisticated knowledge about alternative health-care have all been a part of this change and a cause of the growth of home health-care (Williams et al., 1988).

There has been a movement of health-care out of the hospital into the patient's home. The following section discusses why hospital care has moved to home-care.

1.2.1 Moving health-care into the home

To identify the reasons behind the shift to home care is to understand the point of the development of home-based health-care equipment and industry trends. This section discusses the reasons behind the shift to home care. However, to start with, an

understanding of why health-care originally came to be associated with hospitals is needed.

Stocking (1992) believes that the factors in the development of hospitals were that they were places to care for the poor sick, using improvements in medical technology and providing efficient centralisation of specialist staff and expensive equipment. Many of the advances in medical technology, for example in radiology or in surgical techniques, including anaesthesia, required the use of expensive equipment and facilities by specialist staff. In hospitals, these resources could be centralised and used efficiently.

Several factors are given for the shift to home care by many observers such as Owen, Selinger, Banta, Marks and Stocking. Stocking (1992) lists the following five factors as the main reasons for the shift to home care.

First, there has been an improvement of the home environment - telephone, refrigerators, electricity and good sanitation all make home care more feasible.

Second, there is patients' dislike of hospitals. Though patients will by no means always prefer to be at home; if they are gravely ill, alone and frightened they may well prefer to be in a hospital. Overall, though, with adequate support, most people would prefer to be at home.

Third, hospitalisation itself can be psychologically damaging, particularly to children and elderly people and, of course, the risks of infection are significant in hospitals.

Fourth, two most significant forces towards home care have been changes in the population and financial constraints, and these are inter-related.

Fifth, changes in technology including medical technology have made home care more feasible and manufacturers are developing streamlined, tamper-proof equipment designed specifically for the home care market. This factor is discussed later.

In an economic context, acute care at home has been seen as a cheaper means of providing treatment. However, there are concerns about this. Firstly, although the costs may be less there may be no cost savings unless the level of care in hospitals is correspondingly reduced. On the other hand, hospitals may be used to treat more patients needing more intensive care. Secondly, cost savings may be achieved only at

the expense of families and friends. The burden on carers should not be underestimated, and there are worries that the effects on carers are being ignored.

Above all, economic forces are clearly behind the movement of health-care into the home in all countries. However, different national financial systems may make it easier or harder to support home care or to make savings in hospital care.

Costain and Warner (1992) agreed that there have been some major shifts over time, particularly in the fields of continuing care and chronic illness; for example, care of the elderly, palliative care, care of AIDS patients and the younger disabled. They argued:

Indubitably more highly dependent, ill people are now being cared for at home. What was thought impossible or undesirable 20 years ago is today accepted. It was thought that the question might be turned right round to ask 'How many people need to be in hospital and why?' (p.62)

However, changes are mainly related to the development of day surgery, ambulatory care and shorter hospital stays (Cockerill, 1992). The number of people treated in acute hospitals still continues to increase. Costain and Waner (1992) pointed out that the areas amenable to further shift are rehabilitation, maternity care, mental health-care, and terminal care.

The World Health Organisation (1985) also emphasises in its HFA (health for all) 2000 Target 28 that

the primary care system should provide a wide target of health promoting, preventive, curative, rehabilitative and supportive services to meet the needs of the population.

Various types of support and more active participation by individuals, families and communities are needed to make these changes.

As discussed above, this shift is driven not so much by the technology - which does have a part and is mainly involved in the design and development of home-based health-care equipment - but more by considerations which recognise the limits and disadvantages of hospital based care, and the need for health-care systems to acknowledge the social and environmental components of health (Costain and Warner, 1992).

1.3 Health- care and medical-care and their equipment: definition and status

There are many definitions of home-based health-care equipment. This section discusses health-care, medical care and equipment. The following section discusses home-based health-care and finally gives a clear definition for home-based health-care equipment.

1.3.1 Health-care equipment

Every country in the world has their own system for health-care. This section starts by discussing health-care systems. It focuses on the definition of health-care equipment.

A health-care system is an organised plan of health services. The term is usually employed to denote the system or program by which health-care is made available to the population and financed by government or private enterprise or both (Miller and Keane, 1983).

According to Miller and Keane (1983), the elements of a health-care system embrace the following: 1. personal health-care services available to individuals and families through hospitals, clinics, neighbourhood centres, and similar agencies, and in physicians' offices and the clients' own homes; 2. the public health services needed to maintain a healthy environment: for example, control of water and food supplies, regulation of drugs, and safety regulations intended to protect a given population; and 3. teaching and research activities related to the prevention and treatment of disease.

In general, health-care presents a different problem in every country, for the way it is organised is a response to geography, climate, historical development, economic situation and social, cultural and political conditions.

Cox and Groves (1981) claimed, in the 'advanced' or developed world, there is an established and inherited machinery for medical support and a substantial proportion of national resources is devoted to health-care. The various ways in which this is done range from systems of predominantly private enterprise at one extreme, to complete state provision at the other, with a variety of combinations in between. In the developing countries, on the other hand, there is usually little inherited machinery of a

comparable scale and the provision of health-care has to be built up on almost entirely fresh foundations. Appreciation of these differences is fundamental to the understanding of the situation which prevails in a country.

In the UK, the NHS provides a comprehensive level of different types of care: primary care through family doctors, opticians, dentists and other healthcare professionals; secondary care through hospitals and ambulance services; and tertiary care through specialist hospitals treating particular types of illness such as cancer. At the same time, the NHS works in partnership with local social services departments to provide community care. Almost all these services and facilities are provided free of charge (A guide to the NHS, 1996).

In the United States, the spectrum of health-care has been defined by the Department of Health and Human Services (formerly the Department of Health, Education and Welfare) as encompassing three levels of health-care, namely, primary, secondary and tertiary (see Figure 1-1).

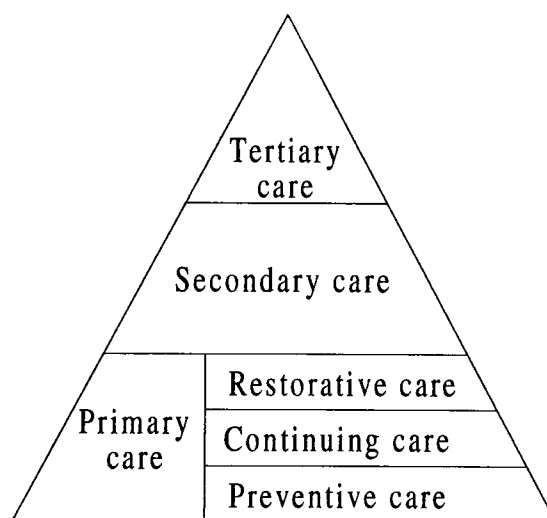


Figure 1-1. The health-care pyramid in the USA

Primary care can be sub-divided into the following cares: preventive care, continuing care and restorative care. Primary care is the usual point at which an individual enters the health-care system. Its major task is the early detection and prevention of disease and maintenance of health. This level of care also encompasses the routine care of individuals with common health problems and chronic illnesses that can be managed in the home or through periodic visits to an outpatient facility. Providers of care at the primary level include family members, as well as the professionals and paraprofessionals

who staff community and neighbourhood health centres, hospital outpatient departments, physicians' offices, industrial health units, and school and college health units.

The first sub divided level of care is ***preventive care***, which is primarily provided by school health education courses and community and public health services.

Restorative care comprises routine follow-up care and rehabilitation in such facilities as nursing care homes, halfway houses, inpatient facilities for alcohol and drug abusers, and in the homes of patients served by home health-care units of hospitals.

Continuing care is provided to support those persons who are either physically handicapped or elderly and suffering from a chronic and incapacitating illness, mentally retarded, emotionally disturbed, or otherwise unable to cope unassisted with daily living. Such care is available in personal care homes, domiciliary homes, inpatient health facilities, nursing care homes, and geriatric day care centres.

Secondary or acute care is concerned with emergency treatment and critical care involving intense and elaborate measures for the diagnosis and treatment of a specified range of illness or pathology. Entry into the system at this level is either by direct admission to a health-care facility or by referral. Provider groups for secondary care include both acute and long-term care hospitals and their staff.

Tertiary care includes highly technical services for the treatment of individuals and families with complex or complicated health needs. Providers of tertiary care are health professionals who are specialists in a particular clinical area and are competent to work in specialised areas such as psychiatric hospitals and clinical areas, chronic disease centres, and the highly specialised units of general hospitals, for example, a coronary care unit. Entry into the health-care system at this level is gained by referral from either the primary or secondary level (U.S. Department of Health and Human Services, 1992).

The principle of referral of patients from a lower level of care to a higher level as a method of sorting them according to their need for specialist diagnosis or the nature or degree of their disabilities is also universally recognised. Less widely recognised perhaps, or at least less widely practised, is a referral system that aims to work in both directions, from lower to higher in the first instance and then in reverse, for example, during convalescence (Cox and Groves, 1981).

As seen above, these are very broad divisions, within which there will be finer gradations depending on the appropriate methods of organisation in a particular country, but as basic categorisations they are recognised and understood throughout the world.

Health-care equipment has been categorised by many people and associations such as the Association of British Health Care Industries (1991). Health-care equipment can be categorised into two main areas, namely, patient-related equipment and laboratory-related equipment. Patient-related equipment and services can be sub-divided into the following headings: aids for the disabled; anaesthetics; audiology; blood bank; cardiology; catheters; cryosurgery; CT (computerised tomography) scanning; defibrillators; dental; diagnostic; dialysis; electrosurgical; electrotherapy; encephalography; endoscopy; ear, nose and throat; infusion; intensive care; neurology; nuclear medicine; obstetrics; ophthalmology; orthopaedic; paediatric; physiotherapy; surgical; and ventilators.

Laboratory-related equipment and services can be sub-divided into these following headings: blood gas monitoring; centrifuges; clinical chemical analyses; microbiological testing; pathological studies; scintillation counters; sterilising equipment; and thermal equipment.

At present, health-care equipment comprises all the equipment which is used for general health-care, but also it normally includes medical equipment (Association of British Health Care Industries, 1991).

By contrast, general use of health-care equipment normally does not include medical equipment. However, the definition of health-care equipment can be defined in terms of their purpose for use.

According to Choi (1995), health-care equipment can be regarded as any equipment or product which is concerned with caring for patients, and which can be used both by the medical professional and the non-medical professional and is different from medical equipment in that medical equipment is usually used by the medical professional only. The following section discusses medical equipment, so that it can be compared with health-care equipment.

1.3.2 Medical equipment

Another term, medical care, has been compared with health-care by Williams & Wilkins (1982). Health-care is that which encompasses the social, economic, and environmental influences, in addition to medical care. Medical care is the portion of care under a physician's direction, and is termed primary, secondary and tertiary.

Primary medical care is the initial contact of a patient with a member of the health-care system such as a paramedic, nurse or physician. Secondary medical care is medical care by a physician who acts as a consultant at the request of the primary physician. Tertiary medical care is specialised consultative care by specialists working in a centre that has a wide catchment area and has personnel and facilities that encourage special investigation and treatment (Williams, & Wilkins, 1982).

In recent years, much medical equipment has been manufactured and used by many people, but there has been confusion in their classification in terms of medical equipment. According to the British Standard Institute (1994), medical equipment can be defined as

A medical device which relies on a power source for its function. A medical device is any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any accessories or software (essential) for its proper functioning, intended by the manufacturer to be used for human beings in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury, investigation, replacement or modification of the anatomy or of a physiological process, control of conception and which does not achieve its principle intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means (p11).

The above definition is identical with that in the European Community Council Directive of 20 June 1990 on the approximation of laws of the Member States relating to active implantable medical devices, with the exception that the word 'essential' is added in the first paragraph (British Standard Institute, 1994).

By contrast, the Medical Devices Agency (1994) claimed that the term 'medical device' covers any product, other than medicines, which is used in the health-care environment for the diagnosis, prevention, monitoring or treatment of illness or injury. The range of products is very wide: it includes contact lenses and condoms, heart valves and hospital

beds, resuscitators and radiotherapy machines, surgical instruments and syringes, wheelchairs and walking frames; many thousands of items used each and every day by health-care providers and patients. The list below is not comprehensive but gives some idea of the wide range of products that are considered to be medical devices (see Table 1-1).

As mentioned earlier, medical equipment is different from health-care equipment, so medical equipment can be defined as any product which is involved with prevention, diagnosis, monitoring, supporting and therapeutics used by professionals only.

Aids for disabled people	Infusion pumps and controllers
Anaesthetic machines and monitors	Infra-uterine devices
Apnoea monitors	Intravascular catheters and cannulae
Artificial limbs	Laboratory equipment
Artificial eyes	Lithotripters
Blood transfusion and filtration devices	Medical textiles, hosiery and surgical supports
Breast implants	Medical lasers
Cardiac monitors	Operating tables
Cardiopulmonary bypass devices	Orthopaedic implants
Clinical thermometers	Ostomy and incontinence appliances
Condoms	Pacemakers
Contact lenses and prescribable spectacles	Physiotherapy equipment
CT scanners	Prescribable footwear
Defibrillators	Pressure sore relief devices
Dental equipment and dentures	Radiotherapy machines
Dental material and restoratives	Resuscitators
Diagnostic X-ray equipment	Scalpels
Dialysers	Special support seating
Dressings and wound healing devices	Sphygmomanometers
Electrosurgery devices	Suction devices
Endoscopes	Surgical instruments and gloves
Enteral and parenteral feeding systems	Sutures, clips and staples
Examination gloves	Syringes and needles
Fetal monitors	Therapeutic X-ray equipment
Hearing aids and inserts	Ultrasound imagers
Heart valves	Urinary catheters, vaginal specula and drainage bags
Hospital beds	Ventilators
Hydrocephalus shunts	Walking aids
Incontinence pads	Wheelchairs
Infant incubators and warmers	

Table 1-1. List of medical devices (Source: MDA, 1994)

1.4 Home-based health-care

The use of medical devices in the home for the treatment and maintenance of patients with acute and chronic (see Figure 1-2) conditions has increased dramatically. While the exact number of medical devices used at home is variable, the following estimates were made by the US Department of Health and Human Services (1992): 19,000 persons dependent on parenteral and tube-administered enteral nutrition, 50,000 to 60,000 infants on apnea monitors each year, 750,000 individuals on respiratory equipment and 2,300 to 17,000 technology-dependent children.

Acute care: Treatment for a serious illness, for an accident, or after surgery. It is usually given in a hospital by trained persons. It may also involve intensive care. This kind of care is usually for only a short time. Compare chronic care.

Chronic care: A type of medical care that concentrates on lasting care of people with long-term disorders. This care may be given either at home or in a medical facility. It includes medical treatment, as well as helping the patients to care for themselves and to eat properly. Physical therapy is also used to prevent loss of function.

Figure 1-2. Acute and chronic care (Source: Mosby's Medical Encyclopedia, 1997)

The provision of acute health-care in the home has received significant attention over the last decade as a possible solution to managing escalating health-care expenditures and as an alternative environment that provides the patient with a higher quality of life. The potential to increase the number of patients being treated at home is largely the result of technological developments that have made equipment either easier to operate in the home or more cost-effective to provide in a home setting (Selinger, 1992).

According to the Council on Scientific Affairs, USA (1990), acute home health-care is defined as 'the provision of equipment and services to the patient in the home for the purpose of restoring and maintaining his/her maximum level of comfort, function and health'.

This definition describes what is being done at home. However, in those countries which already have very developed systems of nursing care in the community this does not make clear the differences which are now taking place.

Marks (1991) defined acute home health-care as ‘*provision in the home of levels of diagnosis and care associated with hospitals*’. Marks’ definition is not just nursing in the community (although nursing care is a likely component of acute home care) but about providing intensive levels of support obviating the need for hospital admission or shortening lengths of stay, and using sophisticated medical technologies at home, and sometimes a combination of both (Stocking, 1992).

Selinger (1992) defined acute home health-care as

treatments at home for the conditions where intravenous therapy includes therapies such as intravenous antibiotics for patients with cystic fibrosis and parenteral nutrition for patients with Crohn’s disease or other intestinal disorders (see Table 1-2).

Selinger has also explicitly included the use of continuous monitoring systems for infants at risk of cot death and adults with heart conditions. This definition of acute home health-care is broadly consistent with Marks’ 1991 definition of ‘*home-based high technology care*’ - ‘*provision in the home of levels of diagnosis and care associated with hospital*’.

Conditions	CAPD/Home Haemo dialysis	Enteral nutrition	Infusion therapy (types)	Monitor ing	Respiratory therapy
Renal failure	X				
HIV+AIDS (acute and Maintenance)		X	TPN (Total parenteral nutrition), antibiotic / fungal / viral pain management		Nebulised Pentamidine
Cancer patients (treat cancer and chemo side effects)		X	Chemo, TPN, Pain management		
Cot death				X	
Cystic fibrosis (4-6 infections/year)			Antibiotic		
Haemophilia (response to acute episodes)			Factor VIII		
Heart function				X	
Hypogammaglobulinemia			Gammaglobulin		
Intestinal failure (Crohn’s)			TPN		
Terminally ill (symptoms)			Pain management		X

Table 1-2. Scope of home health-care available (Source: Selinger, 1992)

As discussed above, home health-care means the provision of health-care services in the patient’s home rather than in an institutional setting or a provider’s premises.

1.5 Technology in home-based health-care equipment

Medical technology refers to techniques, drugs, equipment, and procedures used by health-care professionals in delivering medical care to individuals, and the systems within which such care is delivered (Stocking, et al., 1991).

According to Banta (1992), technology used in home-based health-care includes:

- 1) Medical technology such as dialysis machines, respirators, insulin pumps and devices for controlled infusion.
- 2) Devices to assist personal functions, including moving, reaching, preparing meals and toileting.
- 3) Communication technology (computers, telephone attachments, physiological monitoring and alarm systems) enabling patients to communicate easily with others, including care providers of all kinds.

Banta (1992) has claimed that new technologies relevant to health services will develop and proliferate over the next ten years.

These technologies are even now urgently knocking at our door. At the same time, and in part related to technology, conventional ways of organising and providing health-care will change.

Costain & Warner (1992) state,

It was alleged that technologies which have priority for funding seem to be those that would release beds, making the issue “bed-driven” again. Aids to quality daily living seemed to have lower priority.

The development of artefacts to ease disablement and hasten recovery at home includes products from the entire range of technology. High technology care at home has been described as involving ‘a large medical component’, featuring extensive use of medical personnel in a home setting, into which high technology apparatus may have been introduced (Fox, et al., 1987).

Additionally, Choi (1995) claimed that in the past, equipment such as kidney dialysis, respirators etc., was so big and expensive, and needed special techniques for operation, that they were only used within hospitals. Eventually these became much smaller and cheaper, and easier to use with training, and so can now be used at home. These changes have been made possible as a result of technological advances.

According to Marks (1992) and Brown et al., (1982), technological developments have allowed certain kinds of diagnostic and monitoring devices to be used at home. For example, to monitor arrhythmias, and home apnoea (a temporary cessation of breathing), monitors make it possible for young babies to receive oxygen therapy at home.

Technological advances have also made it easier for people to self-administer advanced therapies. Electronic pumps for infusion therapy regulate dosages more accurately than earlier devices; single dosage packaging of infusion solutions is available; catheters for infusions have been improved and more is known about reactions to nutritional solutions.

In the US, infusion therapy is the fastest growing sector of home care, with costs increasing from \$1.5 billion in 1988 to \$2.6 billion in 1990 (Hafkenschiel, 1990).

The U.S. Council on Scientific Affairs (1990) highlighted some of the advantages of therapeutic care at home:

Tiny computerised pumps allow cancer patients to safely control their own dosage of continuous IV (Intravenous) or subcutaneous narcotics. Babies who use ventilators crawl around their own living rooms; older children tuck their portable ventilators under the wheelchair when they go to school.

As seen above, advanced technologies have allowed health-care equipment to be used at home and have made this feasible. The proper use of technology in the home will also make health-care equipment more useful and effective in the future.

Beekun & Haerens (1992) claimed that requirements for the proper use of technology in the home will include, firstly, requirements concerning patients and their home situation, such as necessary skills; secondly, requirements concerning the quality of the equipment, including ergonomic as well as technical aspects, with emphasis on safety and reliability; thirdly, requirements concerning professional care such as necessary skills and infrastructure, and logistics.

1.6 Definition and status of home-based health-care equipment

This chapter aims to produce practical definitions of home-based health-care equipment. However, few definitions have specifically referred to this type of equipment.

Stocking (1992) and Marks (1991) claim that home health-care equipment use is for renal and peritoneal dialysis, intravenous infusion of antibiotics, cytotoxic or pain-killing drugs, enteral and parenteral nutrition, respiratory therapy, including use of ventilators and oxygen cylinders/concentrators, home monitoring of patients, intensive nursing and rehabilitation therapy.

In discussing home-based health-care equipment, two aspects have to be distinguished, namely, the equipment and the environment, meaning the home. The equipment has commonalties with other equipment used in hospitals but the home environment might allow for people experienced with other forms of equipment to stay in the home environment. For the purposes of this research particularly with reference to Chapter 6, Questionnaire survey with manufacturers, the following 5 part classification of equipment has been used.

First, home levels of diagnostic equipment, intensive levels of support, obviating equipment and monitoring equipment.

Second, therapeutic equipment such as rehabilitation therapy equipment, respiratory therapy equipment, intravenous therapy equipment and infusion therapy equipment.

Third, nursing care equipment, occupationally related equipment.

Fourth, health checks equipment, pain relief.

Fifth, high-tech equipment such as kidney dialysis and blood transfusions.

According to Choi (1995) and Cox & Groves (1981), home-based health-care equipment can be regarded as all health service equipment which is used at home, within the community, and relatively accessible to patients and their families, with the purposes of pain relief, health checks, kidney dialysis, and respirator facilities, etc.

The CDRH (Centre for Devices and Radiological Health) Ad Hoc Home Health Care Committee (1992) has defined home health-care devices as those used in the home environment by persons who are ill or disabled, or whose providers of care need education and/or other related health-care services to use and maintain the devices safely and effectively. According to their definition, infusion pumps, blood glucose monitors and wheelchairs, are included as home use devices, but devices such as pacemakers, pregnancy test kits and tampons, are not.

It is now suggested that a better definition would be: -

Firstly, the equipment is being used within a health-care environment, and is mainly located in a home environment but it also can be used in a general health-care environment such as community or primary health-care environment.

Secondly, the equipment is used by patients themselves, patients' families and health-care helpers rather than doctors or technicians.

Thirdly, the equipment must be operated by a power source such as electricity, battery, etc.

To summarise, the definition of home-based health-care equipment is as follows;

All health service equipment based at home which can also be used in a general health-care environment, operated by a power source and relatively accessible to patients their families and health-care helpers, and where the purpose of use can be associated with hospitals (see also Section 11.2.1, Taxonomy of HBHC equipment).

1.7 Need for design and development in home-based health-care equipment

Landgraf (1992) claimed that current equipment was not suitable for patients and also did not fit with different environments and situations, because the functions of products are not user friendly and technologically suitable. Even though many have claimed that the products, in a broad sense, are beneficial for the users, there is no clear evidence to justify the benefits claimed.

According to Nakamura (1993), many self testers designed for home use have been sold on a commercial basis. However, no formal control of the quality and safety standards of these devices have been made and most of these products are ill-designed. They are not suitable in use in terms of meeting the user's psychological and physical requirements.

Home-based health-care equipment is mainly used by patients and their families at home with no professional assistance, and therefore should be designed to meet the user's real requirements and most importantly it also needs to provide the same quality of services as are provided by medical experts (Monchy, 1992).

The procedures in the design and development of home-based health-care equipment with advanced technology are costly and complex processes, and sophisticated and different from normal commercial product design (Watrous and Zappia, 1993).

In the design and development of home-based health-care equipment, advanced technologies allow product designers easily to encapsulate medical professionals' knowledge into product functions. However, this also needs a careful and extensive study of the user's real needs and their operating environments, concerning the suitability of technical innovations, the economy of product costs, and other psychosocial factors. In addition, selection, assessment of home discharges, delivery, set-up, maintenance and the education of the user also need to be taken into account. This design process entails interviewing actual users, performing a user needs analysis and a task analysis, creating a mental model and gradually forming a user interface specification, as shown in Figure 1-3 (Landgraf, 1992).

Hawker (1992) of Design Technology claims that medical equipment companies are being driven to hire industrial designers by their need to create products which are technically superior, simpler to use, and cheaper to operate. *'There are no cosy corners left for manufacturers to hide in'*, he observes. *'The market is increasingly global and competitive'*. But Hawker also believes that, to be credible, design consultants need to be much more knowledgeable than they generally are about the business needs and manufacturing processes of medical equipment companies; *'in fairness, it must be said that some manufacturers have had bad expertise which has not been up to the demands of medical projects'*.

Medical equipment must comply with numerous safety regulations which vary in different national markets. Electronic equipment demands particular specialist knowledge of issues such as electro-magnetic compatibility.

Harris (1992) of Jones Garrard, a consultancy whose portfolio spans inhalers, drug delivery systems and surgical instruments, warns that companies should choose consultants carefully: *'You wouldn't expect to get the best heart by-pass operation from an ophthalmic surgeon'*. With the right choice, however, the benefits of design in this area are enormous

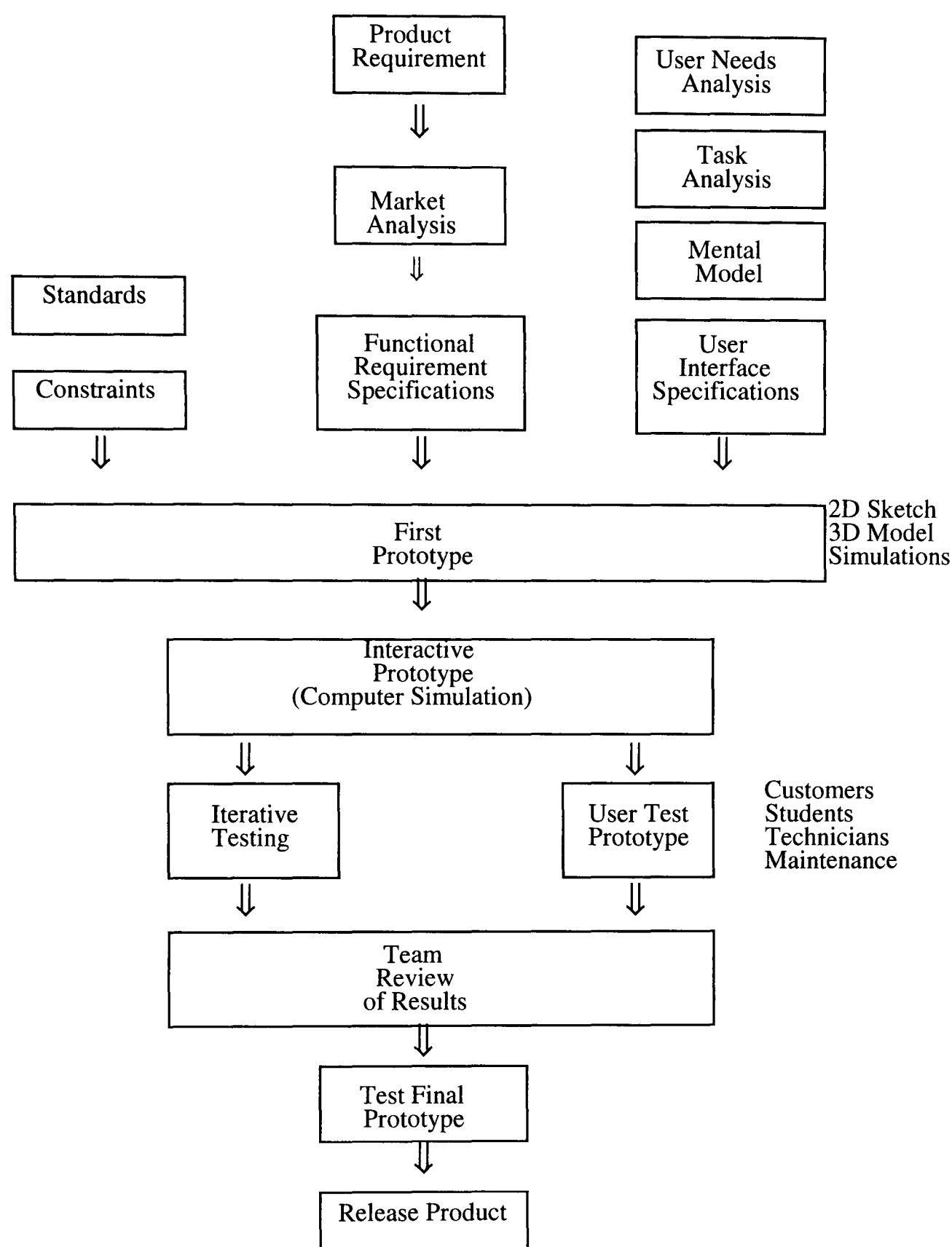


Figure 1-3. Design process flow chart (Source: Innovation, Winter, 1992)

As discussed in this section, much of the existing medical equipment is less well designed than it could or should be due to a lack of appropriate and effective design procedures.

The following chapter will discuss the design & development of home-based health-care equipment.

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Chapter 2

New Product Design & Home-Based Health-Care Equipment

CHAPTER 2 NEW PRODUCT DESIGN & HOME-BASED HEALTH-CARE EQUIPMENT

2.1 Introduction

This chapter starts with a general discussion of design, Section 2.2. Section 2.3 discusses the role of design in new products. Section 2.4 discusses ease of use which is crucial in effective home-based health-care equipment. The remaining sections discuss new product and home-based health-care equipment leading to questions about what this study aims to achieve.

2.2 Design in general

The word ‘design’ originates from the Latin term ‘designare’ which is a compound word with the prefix ‘de’ and the verb ‘signare’, referring to ‘to mark out’, ‘trace out’ and ‘denote’ (The Universal Dictionary of the English Language, 1961).

The Concise Oxford Dictionary of Current English (Fowler, ed., 1995) defines design in four different ways. The first definition is ‘a preliminary plan, sketch, or concept, for the making or production of a building, machine, garment, etc., and the art of producing these’; secondly, ‘a scheme of lines or shapes forming a pattern or decoration’; third, as ‘a plan, purpose, or intention’; fourth, as ‘an example or a completed version of a sketch, concept, or pattern and an established version of a product’.

Meanwhile, the Longman Language Activator (1993) has a more generalised meaning, namely, ‘to decide and plan the way something new will look and work’. It defines design in three different ways, first, ‘to design something’, second, ‘the way that something has been designed’, and third, ‘someone whose job is to design things’.

Lawson (1990) claimed that

‘design’ has become one of those words having such a wide range of reference that we can no longer be really certain just what it means. In different contexts the word ‘design’ can represent such varied situations that the underlying processes appear to share little in common (p. 1).

The term 'design' has gradually come into more general use in our everyday life.

Patric (1973) claimed:

Now that 'Design' is understood from Tokyo to Moscow, from Buenos Aires to Montreal, it is obvious that each country according to its politics, its economics, its sociology, its industry, uses 'Design' in a different way; but one must add that a universal language is being constructed daily (p. 23).

Traditionally, design has been widely accepted as art-oriented activities for increasing the aesthetic appeal of artefacts. 'It is clearly associated with symbols of a fashionable and hedonistic life-style. But it is also about the development of complex engineering components and systems. Sometimes it combines both, conjures up a product, an image of women's fashions, designer clothing, furniture, fabrics and interior design, or even crafts' (Walsh et al., 1992).

However, design is now used broadly to cover a wide range of activities, as follows:

- *Finding the right physical components of a physical structure (Alexander, 1963).*
- *A goal-directed problem-solving activity (Archer, 1965).*
- *Decision making, in the face of uncertainty, with high penalties for error (Asimow, 1962).*
- *Simulating what we want to make (or do) before we make (or do) it as many times as may be necessary to feel confident in the final result (Booker, 1964).*
- *Design in England has become a commodity (Brody, 1992).*
- *Design is 98% common sense and 2% that mystical ingredient that you might call creativity (Conran, 1988).*
- *The conditioning factor for those parts of the product which come into contact with people (Farr, 1966).*
- *Engineering design is the use of scientific principles, technical information and imagination in the definition of a mechanical structure, machine or system to perform prespecified functions with the maximum economy and efficiency (Fielden, 1963).*
- *Design includes the work of people from a wide range of disciplines (Gorb, 1990).*
- *Relating a product with the situation to give satisfaction (Gregory, 1966).*
- *The performing of a very complicated act of faith (Jones, 1966).*

- *The optimum solution to the sum of the true needs of a particular set of circumstances* (Matchett, 1968).
- *Design is more than shape, colour and dimensions of products. Design is the decision-making process that deals with the manifestation of objects with consideration to economy and technical function and in answer to various consumer demands* (Ministry of International Trade and Industry, Japan, 1989).
- *The imaginative jump from present facts to future possibilities* (Page, 1966).
- *Design is the conscious and intuitive effort to impose meaningful order* (Papanek, 1972).
- *A creative activity - it involves bringing into being something new and useful that has not existed previously* (Reswick, 1965).
- *Industrial designers are really the folk artists of our civilisation* (Tiger, 1990).

The problem with these quotations is that they differ so much and cover a wide range of activities. Many of them, however, involve ‘the creative visualisation of concepts, plans and ideas, and the production of sketches, models and other representations of those ideas, aimed at providing the instructions for making something which did not exist before, or which did not exist in quite that form- which might be a building, a dress, a plastic bowl, a machine, a company’s logo or a pair of trainers bearing a company’s logo’ (Walsh et al, 1992; Bruce et al., 1997). There seem to be as many kinds of design process as there are writers about it. Certainly the above quotations give little support to the idea that designing is the same under all circumstances, and ‘the methods proposed by design theorists are just as diverse as are their descriptions of the design process’ (Jones, 1970).

However, according to Gardiner and Rothwell (1985), design is now used broadly to include different activities.

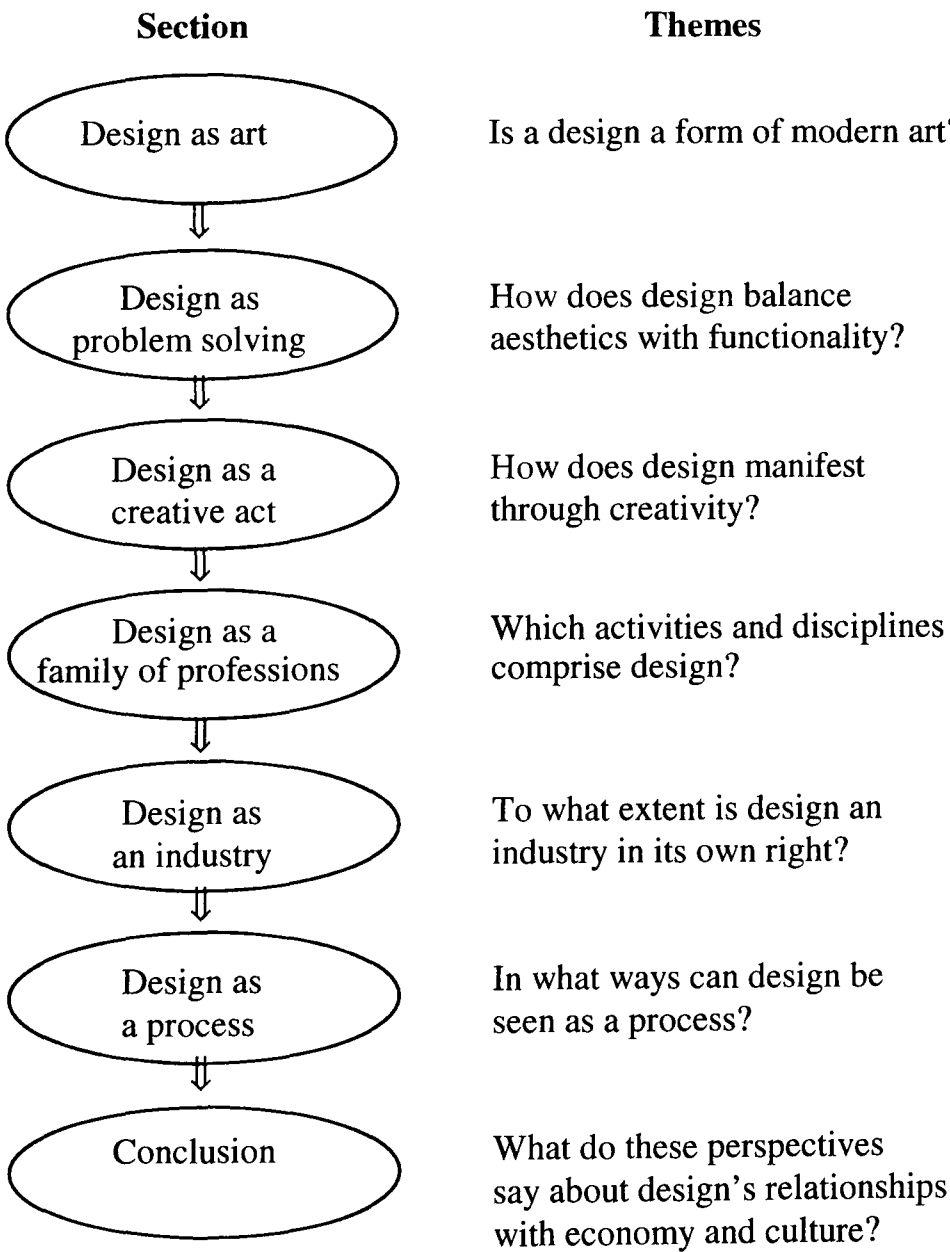
By ‘design’ we do not mean simply aesthetic or ‘industrial design’, but the whole range of design-related activities involved in the creation of a new product or process, viz., engineering design, production design and aesthetic design.

Cooper and Press (1995) defined design in terms of six different activities: design as art, problem solving, creativity, a family of professions, an industry and as a planning process (see Figure 2-1).

They added that the nature of design is defined by the evolving interrelationship between economy and culture.

Design's nature evolves in relation to changes in the mode of production and in the context of cultural and social development. It has become more complex and specialised over time. Consumer culture and the ideology that championed it in the 1980s made design a more market- oriented and managed process. This had negative consequences in terms of design's commitment to quality and the social interest that it served. However, some critiques of design's role in this period have neglected the positive potential of consumption as a cultural activity. A fuller view of design's role is gained by analysing its value in commercial, symbolic and social terms (p. 47).

Figure 2-1. Six different activities (Source: Cooper & Press, 1995)



‘Design’ means different things to different people. Depending on their point of view, design can have different meanings. Design can be viewed as a discrete activity, or as a total process or in terms of its tangible outcome. It can also be viewed as a management function, a cultural phenomenon and as an industry in its own right. Design is defined differently in different countries, with our understanding of it changing over time (Cooper and Press, 1995).

2.3 Design and new products

The fact that design involves planning something new provides a link with studies of new products. Walsh et al. (1992) claimed that since ‘design’ and ‘innovation’ are similar activities, one frequent source of confusion is that design and innovation can mean either,

An activity - the design process or the innovation process.

Or:

The outcome of that activity - ‘a design’ meaning an idea or a plan from which an object can be made, or the form of the object itself; ‘an innovation’ meaning a new product or industrial process when it first appears on the market or enters into use (p. 15).

According to Freeman et al. (1982) the innovation as outcome is defined as ‘the first introduction of a new device, product, process or system into the ordinary commercial or social activity of a country’.

However, Walsh et al. (1992) claimed that innovation as activity is frequently also used to describe the whole activity from invention (discovery of the new device, product, process or system) to the point of first commercial or social use.

Walsh et al. (1992) claimed that design is the vital link between a market need, an invention or innovative idea and its translation into a product suitable for manufacture and use. Good design can contribute towards improved business performance but cannot guarantee success. Putting effort and resources into design and product development is a necessary, but not a sufficient, condition for competitiveness and good business performance at the company level as well as for an improved trade balance and

growth at the level of the national economy. 'To be effective, design must be integrated with other aspects of product development, especially marketing and manufacture' (Walsh et al., 1992).

Cross (1989) views design and development as the core of new product development or the innovation process: in other words, the stage in which market needs or opportunities identified in a brief are transformed into detailed instructions for manufacturing a product.

A survey by Walsh et al. (1992) shows that the most successful firms usually have a strategy,

'for example, market-led continuous evolution of existing product design or technology to create or exploit existing products combined with a longer term programme of innovation in product design or technology to create or exploit new market demands. In other words, these firms are not afraid to run the higher risks of producing products that may be ahead of market demand or that make use of innovative design ideas or new technologies' (p. 8).

Cooper and Press (1995) and Bruce et al. (1997) defined design from a marketing perspective. They claimed that marketing and design are interdependent. Design is related to every aspect of the marketing mix, in other words, design interfaces with different parts of an organisation to help produce 'the right product, at the right place and price, at the right time' (Bruce et al., 1997).

Cooper and Press (1995) claimed that the critical nature of the design-marketing interface means that market research must be undertaken in such a way as to inform designers both quantitatively and qualitatively about the end users of their design, e.g., to supply market sizes, customer profiles and lifestyle information. Bruce et al. (1997) added that designers need to have some insights into the factors influencing consumers' buying decisions, as well as competitor analysis and the organisation's objectives for the project.

Research and development (R&D) feeds design with information on new technologies, new materials and processes. Design can guide R&D on potential research directions for new products. Cooper and Press (1995) suggest that there are three key functions in new product development; first, marketing, second, design and technology, in other

words, people, third, materials and processes. How these are managed to relate with one another is known to be important to the success of new products. Whatever is meant by 'design', for most people it clearly relates to new products. The next section discusses new products in more detail.

2.3.1 New products

New products can involve different levels of newness ranging from completely new to a very minor change (Chang, 1993). Thomas (1993) defined a new product in two different ways. The first definition clings to its absolute sense, 'something that is new that has not existed before', the second in a relativistic sense, 'something new that has not been experienced before' - it is perceived as new. In a sense, the second definition may represent opportunities (or problems) for consideration.

According to Buck (1963), there are five different kinds of new products, namely, a completely new product, a product new to the organisation, a technically improved product, a product with changed appearance and a product with a different price. Further, Booz, Allen and Hamilton (1982) offer six types of new products in terms of their newness to the company and to the market-place. They are new-to-the-world products, new product lines, additions to existing product lines, improvements in or revisions to existing products, repositionings and cost reductions.

Crawford (1987) identifies nine types of new products which depend on newness to whom, viz., the newness of the product to the firm, the newness of the product to the market-place, the newness of the product as perceived by buyers or users, and miscellaneous criteria which include changes mainly in function (see Figure 2-2).

Figure 2-2 Nine types of new products (Quoted from Crawford, 1987)

1. A product performing an entirely new function, such as television, which for the first time permitted the transmission of audio-visual signals.
2. A product that offers improved performance of an existing function, such as a wristwatch whose balance wheel has been replaced by a tuning fork.
3. A product that is a new application of an existing one. For example, the aerosol bomb, which was first developed for insecticides, and was later applied in paints, etc.

4. A product that offers additional functions. The hands-free telephone, for example, does what the earlier telephone did, plus more.
5. An existing product offered to a new market. This may be done, for example, by repositioning or by taking a regional brand into other regions.
6. A product that through lower cost is able to reach more buyers. Hand calculators are an example.
7. An upgraded product defined as an existing product integrated into another existing product. The clock-radio is an example.
8. A downgraded product. For example, a manufacturer markets a component that had previously been purchased.
9. A restyled product. Annual auto and clothing changes are examples.

As seen above a 'new product' may be seen in slightly different ways. A PhD. thesis by Chung (1989) defined types of product changes in terms of the newness of technology involved and the newness of the market. Chang (1993) further added the newness perceived by consumers.

Chang (1993) claimed that modified products could cover those being perceived as new products by consumers and those not perceived as new. Changes are often seen as aspects of function, use, style, cost or combinations of these changes. He categorised five different types of changes as improvement in function, improvement in use, change in style, change by reduction in cost and combinations of these changes

As discussed above, new products involve many types of newness. In many cases, changes seem to produce products that are difficult to use and unfamiliar to the user.

Above all, the most significant issue for this study is that changes in technology including medical technology have made home care more feasible and manufacturers could be expected to be developing streamlined, tamper-proof and generally improved, easier to use equipment designed specifically for the home care market.

There are, however, difficulties in this trend, some of which may be associated with problems in using the equipment. For example, Berman (1986), reported that many types of ventilator are badly designed.

The worst examples of badly designed products, installed at Whipps Cross, are to be found in the Intensive Therapy Unit itself, where patients are to be found strung up to a mass of tubing, surrounded by machines. There is no system for

stacking the equipment or ducting all the tubing and wiring. All manufacturers are different, there's no uniformity, even of plug sockets (p. 29).

In some cases, six months' training is required before home users are considered competent to use certain HBHC equipment. In other cases, equipment that could technically be used at home is not considered appropriate because of its complexity or risk of 'doing the wrong thing' by the user. There would, therefore, be considerable gains if equipment controls could be made easier and safer to use. Ease of use is a crucial aspect of product design in general and especially in home-based health-care equipment design

The following section discusses design for ease of use.

2.4 Design for ease of use

Langrish and Huang (1996) claim that both new technology and new design can create problems in use. A comprehensible product is a practical requirement for people's daily lives. Krippendorff (1989) indicates that the understanding of something is always the key to its practical use.

Norman (1988) describes many daily examples of the problems caused by ambiguous design. Poor design causes unnecessary problems for their users, such as getting trapped in double doors, confusion with combined hot and cold water taps, bad mapping arrangement of burners and controls on kitchen stoves, difficulties in operating video-cassettes and washing machines etc. He claims that the designer must allow for the user's mental mechanisms and psychological concepts in the design conceptualisation. Krippendorff (1984) also points out that poorly designed products may cause disastrous mistakes when they occur in emergency equipment, fire extinguishers, escape doors, emergency buttons etc., that must be located and identified, often under stress situations.

Berman (1986) claims one of the trickiest instruments to design is a ventilator which pumps air into the patient's lungs, acting as a breathing apparatus.

If the patient is accidentally disconnected, the consequences could be deadly. This is why a complex set of alarms are usually triggered if the machine is turned off accidentally, if the patient moves suddenly and loses the connection, or if

someone trips over the wire and it becomes unplugged. And there is the further problem that when the nurses have to attend to a patient, they turn off the alarms, and may forget to turn them back on (p. 29).

Lin (1996) claims that an important factor in improving the usability of objects is an awareness of the differences between the user's meanings and the designer's meaning. It is important to have a 'user-friendly' design which means 'user-oriented' design. It is therefore, important for a designer to consider the user's way of coping with their objects. He argues that designers must be knowledgeable about how the intended meanings are reflected in the designed products (Lin, 1996).

2.4.1 Affordance

The term 'affordance', was developed by Norman (1988) using the ideas of Koffka (1935). This section discusses the affordance which is concerned with the kind of messages that relate to the use of products. Koffka (1935) believed that the meaning of objects is an invitation which elicits people to know what to do with them. In his words: *'Each thing says what it is. A piece of fruit says, "Eat me", water says, "Drink me", thunder says, "Fear me", and a woman says, "Love me"'*. Langrish and Huang (1996) claimed that, *'The post-box invites the mailing of a letter, the handle wants to be grasped and things tell us what to do with them'*. This approach was used by Gibson (1979) in his theory of 'affordances', a crucial aspect of which is the idea that the affordance ('eat me' etc.) is a product of the relationship between the object and the viewer and not a product of some intrinsic quality of the object.

The theory of affordance states that 'objects (natural as well as manufactured) give messages about what they can be used for. These messages are a product of the interaction between the observer and the object rather than being completely dependent on the form of the object' (Gibson, 1979).

Norman (1993) claimed that the affordance of an object refers to its possible functions. For example, a chair affords support, whether for standing, sitting, or the placement of objects; a pencil affords lifting, grasping, turning, poking, supporting, tapping, and of

course, writing. He further claims that affordance also applies to technologies. Different operations are afforded by different technologies.

In design, the critical issue is perceived affordances, in other words, what people perceive the new products can do. Objects are used by people in ways suggested by the most salient perceived affordances, not in ways that are difficult to discover. Hence, many owners of electronic devices often fail to use some of their most powerful features that some people often never even know exist (Norman, 1993).

Norman (1988) claimed that there already exists the start of a psychology of materials and of things, the study of affordances of objects. He stated that affordance refers to the perceived and actual properties of the thing, primarily those fundamental properties that determine just how a thing could possibly be used. He also believes affordances provide strong clues to the operations of things such as 'plates are for pushing', 'knobs are for turning', 'slots are for inserting things into', 'balls are for throwing, bouncing or rolling'. When affordances are taken advantage of, the user knows what to do just by looking: no picture, label, or instruction is required. Complex things may require explanation, but simple things should not. When simple things need pictures, labels, or instructions, the design has failed.

Most people learn through experience but when a new product appears, experience may be lacking. Three ways to tackle this problem in new products are:

1. by analogy to other products
2. through understanding a more fundamental 'language' of how things might or should operate, namely, semantics. This can be seen as development of 1. analogy to other products.
3. also by trial and error - producing desired results (this being anticipated by the designer as a learning strategy by the user). Obviously, this third option is not available in areas where error can lead to death!

The next section discusses this second approach, design semantics, in more depth.

2.4.2 Semantics

Two different sources of ideas have contributed to product semantics for use; firstly, semiotics, as used, for example, by Umberto Eco who applied semiotics to architecture and secondly, the theory of affordances (Gibson, 1979). Krippendorff (1984) combined the above concepts and as a result of considering their implications for use, he suggested three 'laws' of product semantics for use:

1. A product should announce what it may be used for.
2. If someone wants to use it, the product should state how to start.
3. The product should provide feedback that it is being used correctly.

(Krippendorff, 1984)

Many everyday products including HBHC equipment failed to meet at least one of 'Krippendorff's laws'. Several researchers have studied the reasons for these failures and ways to improve things (Langrish and Huang, 1996; Langrish and Lin, 1992). They identified three reasons for these problems. Langrish and Huang (1996) asked 'Why are new products difficult to use?' Some answers are as follows:-

1. Industrial Management. New product thinking concentrates design on the purchase decision rather than on use. Strategies to compete by design for ease of use are noticeable by their absence. Most new product strategies involve extra functions rather than fewer. In the few cases where management is aware of the power of product semantics (e.g. Blaich, 1989), messages about 'life style' differentiation and market niche are looked for rather than messages about use. The streamlining of TV design has led to the 'ludicrous position where there are problems even with switching on and off'.
2. Design. Neither engineering designers nor industrial designers are motivated to tackle the control problem. Engineers get fun out of the latest extra function and 'artistic' designers like creative novelty and what they call 'sexy' design. There is a danger that designers design for other designers rather than the public. Both types of designers are capable of producing easy to use products but they are not set this task. Norman (1988) has identified many confusions and frustrations present in modern products. He claims that manufacturers do not recognise the problem. They say 'We have not had any complaints'. Norman claims that people do not complain because they assume that it is their fault for being stupid rather than bad design.
3. Technological Change. Change has affected the way that products have a 'language'.
 - a) Many products no longer 'have to be' the way they are. This is partly due to the well known electronics revolution, for example the old mechanical alarm clock can be compared with the modern electronic version. The key for winding the spring was the shape, because torque needed to be applied to the spring. The control for turning the hands of the clock did not need to have such a turning movement and was therefore a different, easily recognised shape. The bell on top of the clock announced what it was. All this has been replaced by confusion.

Other technological changes have caused similar problems. One of these is the change from pressed metal to moulded plastic. In old metal-bodied torches, for example, a screw cap at the end of the

barrel handle announced that it was a screw cap. Because it was pressed out of metal the screw thread showed on the outside as well as the inside. Moulded plastic threads, however have no such outward sign. If you want to change the battery of a modern torch, how do you open it? Our records show that in many cases the answer is 'with difficulty'.

- b) Technological change in methods of production has made it easier to change the features that used to act as the product languages. Spoken language takes time and stability to learn. Similarly, you can not learn a product language if designers and marketing people keep changing the design without even being aware that they are changing the language of use.
- c) Technological change has produced many more sequential and spatial problems. The Apple Mac and its imitation, Windows, have shown that it is possible to use design to reduce these problems but such thinking has not yet been applied to washing machines, microwave ovens etc.

(Quoted from Langrish & Huang, 1996)

Langrish & Huang (1996) claim that there is a clear need for products that are designed to be easy to use. They believe that industrial designers with an interest in product semantics for use can achieve this.

No major manufacturer has yet realised the existence of a new strategy. Why not?

Product semantics concerns itself with conveying information. Kron (1987), the winner of the 1987 Forma Finlandia Plastics Competition with her answering machine 'Phonebook', said,

Like most design of electronic products, I found the toughest part was to deliver new technology to the user with a minimum of alienation and a maximum of understanding.

Baily (1993) claims that designers not only provide the product with visual, tactile and sensory features, but also imply status through the use of certain materials and colours to increase the motivation to buy, for example, arousal of customer's desire, being the possessor of a sophisticated and high -technology product, visual and tactile senses.

Blaich (1989) claimed,

Semantic theories were to be applied to make the products more readily understandable, and easier and safer to use. The product studies sought to express the product's structural and functional components, but they also clearly communicated the social, cultural, psychological and sensual aspects of the product. Visual metaphors were to be used to achieve the desired social value of the product.

Norman (1986) claimed that the 'design model' and the 'user's model' is the user's mental model developed through interaction with the system (see Figure 2-3). The system image results from the physical structure that has been built (including

documentation, instructions, and labels). The designer expects the user's model to be identical to the design model. But the designer does not talk directly with the user – all communication takes place through the system image. If the system image does not make the design model clear and consistent, then the user will end up with the wrong mental model. As a result, when the system image is incoherent or inappropriate, a break-down of the interaction between the user and the system can be expected.

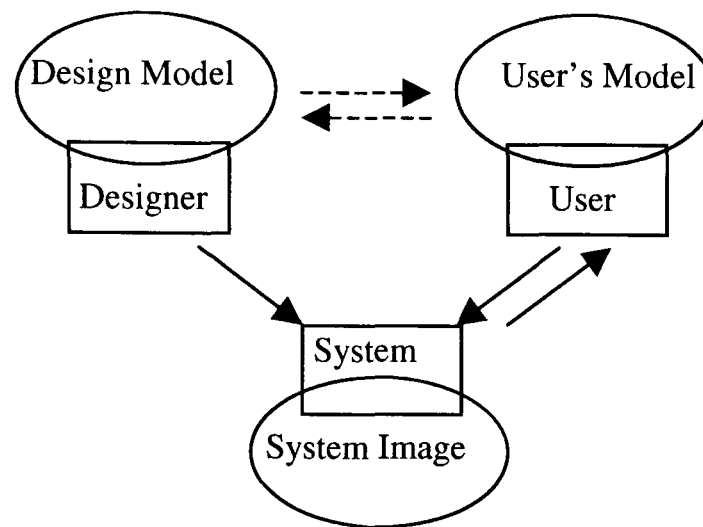


Figure 2-3. Communication processes in design (Source: Huang, 1996, based on Norman, 1986)

With reference to Figure 2-3, Huang (1996) claims that connecting the communication gap between the designer and the user (dotted lines) might help to provide the designer with a better design model which is consistent with the user's model. Thus a system which copes with the user's mental model might be expected from the designer.

Norman argued that the designer should be responsible for the failure of the use of many ordinary products. However, the above explanation provides only part of the answer. Huang (1996) claims, based on the above model, that apart from the designer and the user involved in the model, a third person, who might influence the model the manufacturer needs to be mentioned. He believes manufacturers, who provide resources and, therefore, are more likely to be the controllers of the new product development process, were not considered in this model.

The manufacturers' attitudes towards design might influence the thinking of the designer which in turn would affect the outcome of the product, in this case, the system image. It is therefore of interest to investigate the manufacturers' attitude towards design. Manufacturers seem more interested in their customers, i.e. the purchasers, than the users (Huang, 1996).

This is particularly important when purchasers and users may be different people, as is the case with equipment purchased by hospitals for use in the home.

2.5 New product & home-based health-care equipment

Nakamura (1993) pointed out that much of this type of HBHC equipment sold on a commercial basis is newly designed and recently produced with advanced technologies, involving a complex and costly development process. Subsequently, it is intrinsically difficult to comprehend the real concepts and scope of home-based health-care equipment.

‘Medical equipment design must be able to look after the physical, psychological and social needs of the patient’ (Monchy, 1992). The doctor-centred disease-oriented approach sees the doctor as the most important person and feels that medical design is high technology used for improving the efficiency of curing patients. In contrast, the patient-centred problem-oriented approach sees doctors and patients as equals and regards medical equipment design as more friendly and less threatening to the patient, particularly in the design of home-based health-care equipment (Monchy, 1992).

According to Nakamura (1993), 50% to 70% of the medical devices sold on the market, such as sphygmomanometers and blood sugar testers, are difficult for many patients to use despite their high accuracy in operation.

In the design and development of home-based health-care equipment, advanced technologies allow product designers to encapsulate medical professionals’ knowledge into product functions. However, this also needs a careful and extensive study of the users’ real needs and their operating environments, concerning the suitability of technical innovations, the economy of product costs, and other psychosocial factors (Shaw, 1988). In addition, selection, assessment of home discharges, delivery, set-up, maintenance and the education of the user also need to be taken into account (Watrous and Zappia, 1993).

This design process entails interviewing actual users, performing a user needs analysis and a task analysis, creating a mental model and gradually forming a user interface specification (Landgraf, 1992). Much of the existing medical equipment is ill-designed due to a lack of appropriate and effective design procedures. However,

changes in medical technology have made home care more feasible and manufacturers are developing streamlined, tamper-proof equipment designed specifically for the home care market (Stocking, 1992).

It is recognised that industrial designers can play a very important role in improving the overall design and development of new home-based health-care equipment, particularly in the area of employing advanced technology (Cockerill 1992). Home-based health-care equipment is not unique in having user problems. Surveys of washing machine users, for example, show that many users have problems with the controls.

It follows, therefore, that the specific study of home-based health-care equipment might have a wider relevance to the general area of designing more effective new products. This research, therefore, seeks to discover the benefits and deficiencies of using home-based health-care equipment and to identify the major deficiencies of current design procedures. Consequently, the next chapter discusses the research methods used to achieve the above aims.

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Chapter 3

Research Methodology

CHAPTER 3 RESEARCH METHODOLOGY

3.1 Introduction

This chapter begins with an overview of research issues, including qualitative and quantitative research, and the case study approach, Section 3.2. Next, there is a review of related literature, Section 3.2. Section 3.4 describes how the questionnaire surveys and interviews were conducted, and the processes involved in approaching organisations and hospitals. The following sections, Sections 3.5, 3.6 and 3.7, describe how the case studies were prepared, namely, criteria for the choice of case studies, the selection of participating organisations and the case-study scheme design; in addition, how the case studies were conducted with three selected organisations. The final section, Section 3.8, discusses the analysis and synthesis of results, utilising ‘Grounded Theory’.

The title of this research is ‘The Role of Design in Home-Based Health-Care Equipment’. The aims of this research are:

1. To produce a taxonomy of medical equipment leading to a practical definition of home-based health-care equipment.
2. To discover the benefits and deficiencies to the user of using home-based health-care equipment.
3. To identify deficiencies in the design process of home-based health-care equipment.
4. To add to the understanding of how design has an effect on new products.

The title of the research originally approved by the Research Degrees Committee of De Montfort University was ‘The Role of Industrial Design in Home-Based Health-Care Equipment’. In the manufacturer survey, out of 56 people working in in-house design teams, only 5 were industrial designers (see Chapter 6, p.222). It was therefore decided to change the title by replacing ‘industrial design’ with ‘design’ and to change Aim 4, which had originally been; ‘to add to the understanding of how industrial design can improve the effectiveness of using new products’.

During the course of the research, it was decided to change Aim 3 from ‘design’ to ‘design process’, since it was found to be more appropriate if Aim 2 covered the product and Aim 3 covered the process. Therefore, Aim 3 changed from its original statement, namely, ‘to identify deficiencies in the design of home-based health-care equipment’.

3.2 An overview of research methods

An overview of the research design is shown in Figure 3-1. It illustrates the connections between research elements in the background research stage and those of the main research study. These are discussed in greater detail later in the chapter. This research used a questionnaire, interviews and documentary sources as complementary techniques to obtain the information, including views and opinions, about the users' opinions for using home-based health-care equipment and how companies obtain and convert these opinions into design specifications, and in each case, if they do actually obtain users' opinions. Three case studies of manufacturers were carried out to obtain more detailed information. The rest of this section is a general discussion of research methods.

Howard and Sharp (1996) defined the word research as

seeking through methodical processes to add to one's own body of knowledge and, hopefully, to that of others, by the discovery of non-trivial facts and insights.

According to McNeill (1990), research is fundamentally prompted by simple human curiosity, an indispensable quality if research is to be both successful and enjoyable. The importance of a piece of good and successful research needs seriousness and continuous commitment. Leedy (1997) further argued,

Research is not mere information gathering nor a mere transportation of facts from one location to another. Research is a procedure by which we attempt to find systematically, and with the support of demonstrable facts, the answer to a question or the resolution of the problem. This procedure is frequently called 'research methodology'.

According to Easterby-Smith et al. (1991) there are three reasons why an understanding of philosophies in the social sciences may be useful for researchers. A knowledge of philosophy can help researchers to clarify research designs, and to recognise which experimental methodology will work and which will not, and to identify or even create designs that may be outside their past experience. It may also help researchers to adopt research designs according to the constraints of the different subject or knowledge structures.

For a long period there has been debate in the social sciences about the most appropriate philosophical position from which methods should be derived. One is positivism, and the other is anti-positivism. Many different variants are associated with anti-positivism, such as phenomenology (Easterby-Smith et al., 1991), hermeneutics, and naturalistic inquiry (Henwood and Pidgeon, 1993).

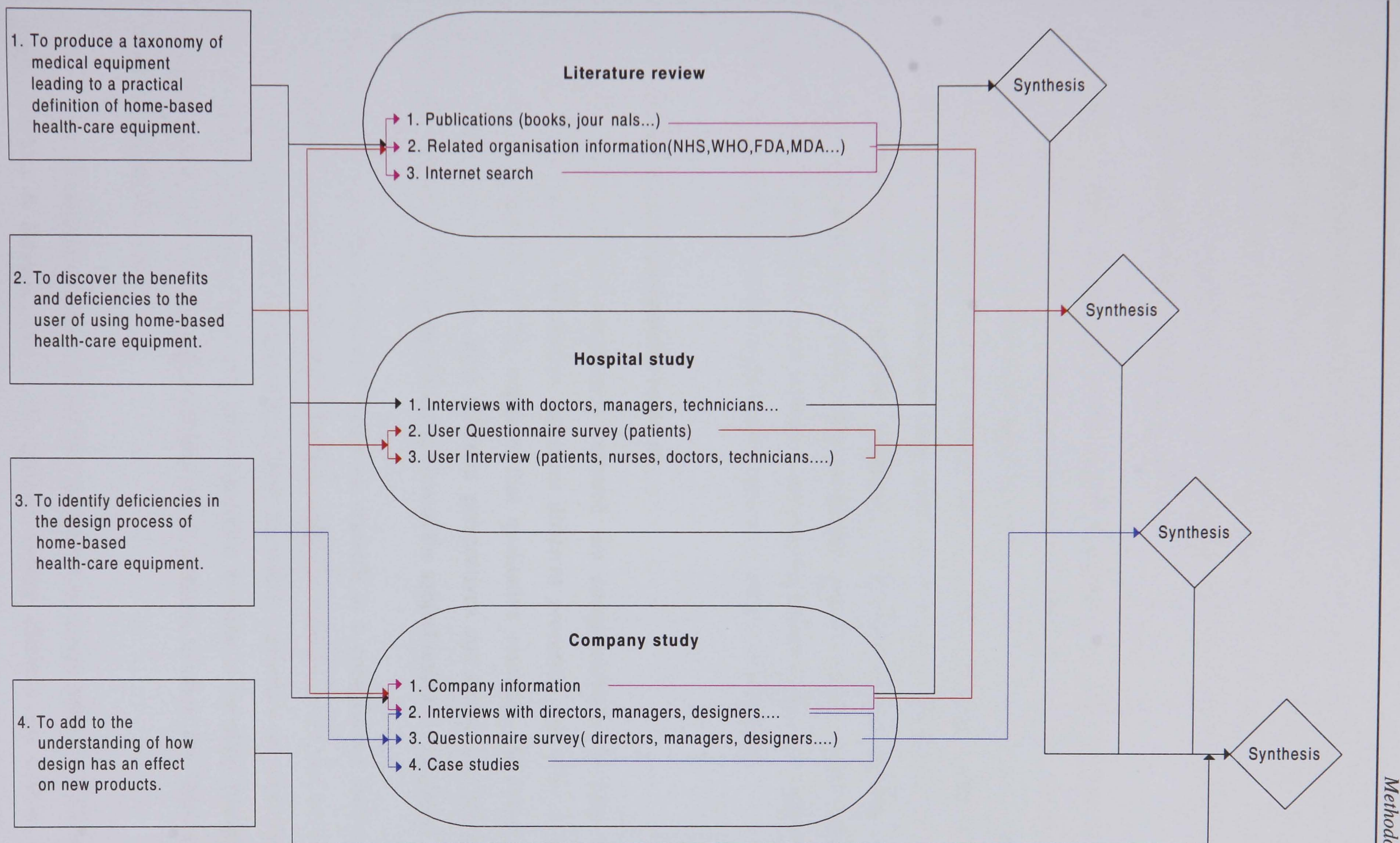


Figure 3-1. PhD research plan overview

Positivism argues for research following the sequence of the hypothesis and the testing and confirmation or otherwise, of the hypothesis, while, anti-positivism provides guidelines about how the researcher should conduct his endeavour, to focus on meanings, to try to understand what is happening, and to develop ideas through induction from data (Easterby-Smith et al., 1991).

Hammersley (1993) claims that within social research there are tensions between research modelled on the practices of natural science and between ideas about distinctiveness of the social world and implications of this and how it should be studied. This tension is often presented as a choice between two conflicting paradigms and whilst the names of these paradigms often differ, there is considerable overlap in the content among the various accounts (Johnson, 1976; Schwartz & Jacobs, 1979). According to Hammersley (1993), these paradigms can be called ‘naturalism’ and ‘positivism’. A positivistic focus favours a quantitative research approach whereas the naturalistic paradigm promotes a qualitative approach, such as ethnography.

3.2.1 *Qualitative and quantitative research*

Qualitative research and quantitative research are complementary to each other, although both research approaches represent different processes and have different procedures. Halfpenny (1979) suggests that qualitative research and quantitative research can view a subject from different perspectives and hence the sources of information obtained allow a more holistic view of the subject under investigation.

The distinction between these two forms of research is a complicated matter. As Warwick and Lininger (1975) stated, ‘*Each is useful for some purposes and useless for others*’. So there should be a process strategy to enable a selection of methodology. However, in a new area, it is not always possible to have a carefully thought-out strategy. There has to be enough flexibility in the methods to allow for surprises and obstacles (Langrish, 1996).

One version of qualitative research that has been used in design research is Grounded Theory (Glaser & Strauss, 1967). An updated version (Strauss and Corbin, 1997) defines grounded theory as a comparative method concerned with generating and

developing categories, properties and hypotheses rather than testing them. It can also give the intricate details of phenomena that are difficult to convey with quantitative research.

The type of research which is based only on postal surveys has several well known problems (Cohen and Manion, 1994). For example, Glen and Lord (1996) sent a postal survey to 800 firms in the UK medical device industry and obtained 113 useful responses. These responses provided no information about the difference between customers and users which more open-ended methods would have revealed to be very important.

Greensides (1996) claims, *Questionnaires have numerical aspects but they usually involve questions and opinion based answers which are essentially 'qualitative'*.

Langrish (1993) argues that the true distinction between qualitative and quantitative research is concealed by reference to the absence or presence of numbers. He divides research into two research traditions: physics and biology. He argues the differences in concepts between these two are that the physics approach looks for 'underlying principles' and 'mathematical equations', whilst the biological approach 'glorifies diversity' and looks for taxonomies. He further points out that the biological approach views things as 'caused' by their objectives and argues that 'design is biological and design research should use a philosophy closer to this biological approach'.

Considering the various available research methods and their advantages and disadvantages, it was decided that this study required both quantitative and qualitative methods, also called a multi-method (Cohen and Manion. 1994). The major methods employed for this research were questionnaire surveys which were intended to produce both qualitative and quantitative data, while the qualitative method was carried out through semi-structured interviews used to support the surveys. These methods were chosen and used to complement one another, in what is sometimes called 'triangulation' (Borg and Gall, 1996).

3.2.2 The case study approach

A case study research method provides a useful introduction and is generally used when the investigator has little control over events and when the focus is on some real-life context. Lawrence (1951) described a case study as 'a chunk of reality' which is 'the anchor on academic flights of speculation'. Langrish (1993) added that the case study, from the sense of what is meant by research, is

a way of finding out more about some aspect of reality through a very detailed analysis.

According to Yin (1994) a case study can be seen as, an empirical inquiry that investigates a contemporary phenomenon within its real-life context when the boundaries between phenomenon and context are not clearly evident and in which multiple sources of evidence are used. Yin (1994) stated that case studies are the preferred strategy when 'how' and 'why' questions are being posed and often relate to an analytical case study, although exploratory and descriptive case studies can also be used, either singularly or to complement one another. Cohen and Manion (1994) claimed that the case study observes the characteristics of an individual unit in order to probe deeply and to analyse intensely the diverse phenomena that constitute the life cycle of the unit with a view to establishing generalisations about the wider population to which that unit belongs.

According to Bryman (1992b), case studies can serve three different purposes in addition to permitting the generation of theory. Firstly, they can be employed in a somewhat exploratory manner in order to achieve insights into a previously uncharted area. Secondly, they can be used in order to test theories. Thirdly, they can allow the findings from other studies to be confirmed. Sypher (1990) also claimed that the purpose of a case study is

to describe real-life events in such a way (phenomena should be examined in their natural setting as they naturally occur) so as to enhance our understanding and to bolster our insight in ways that other methods could or normally would not do.

This means that the case study is useful for providing an understanding of phenomena and is more flexible.

Langrish (1993) claimed, in ‘adding up’ the knowledge, that the strengths of the case study approach are three-fold. In his own words,

Firstly, cases add detail to previously known phenomena (in an anatomical analogy they add knowledge of the flesh to a skeleton developed by questionnaires). Secondly, they discover new phenomena (general or unusual, like circulation of the blood or internal cancers). Thirdly, they can refute existing notions such as the importance of a detailed design brief in the process of new product development.

Hakim (1987) pointed out that case studies are

a useful design for research on organisations and institutions in both the private and public sectors, and encompass studies of firms, workplaces, schools, trade unions, bureaucracies, studies of ‘best practice’, policy implementation and evaluation, industrial relations, management and organisation issues, organisational cultures, process of change and adaptation, extending to comparative studies of nations, governments and multinationals.

From the techniques of data collection, Yin (1994) emphasised that the case study’s unique strength is its ability to deal with a wide variety of evidence. Case studies provide one of the chief arenas in which quantitative and qualitative research can be combined. Case studies involve more than one approach to data collection (Bryman, 1992b).

A case study approach for this research was chosen not only because of its strengths and advantages, but also because of the essentially exploratory nature of the research. Home-based health-care equipment design is a new area where a theoretical basis is still being developed. The research is, therefore, of an exploratory nature, aiming to obtain opinions of users in order to gain information about the benefits and deficiencies to the user of using home-based health-care equipment and to identify deficiencies in the manufacturing design process of home-based health-care equipment.

It is important to note that this research does not aim to test or explore any existing theory, primarily because of the lack of established theory in this area of design. Rather, it is concerned with obtaining a clear view of this new subject area, through a literature review, questionnaires, interviews and case studies.

3.3 Literature search

The aims of the literature search were to achieve the following objectives:

1. To produce a taxonomy of medical equipment leading to a practical definition of HBHC (home-based health-care) equipment.
2. To gain a structured understanding of the various types of HBHC equipment.
3. To identify deficiencies in the design of HBHC equipment.
4. To gain an understanding of the role of design in new product development.

Only a small amount of literature on home-based health-care equipment was identified.

This indicates that the analytical discussion of home-based health-care equipment is rather new to academic review and publication. The types of home-based health-care equipment are therefore set out and discussed systematically, evolving a definition of home-based health-care equipment which is provided in Chapter 1 of this thesis. Chapter 1 contains a part of the results of efforts to achieve the first and second objectives above.

At the start of this research, a wide range of literature dealing with design theories, new product design, design semantics, design management, cognitive psychology etc., was studied in order to provide background knowledge of general product development, ease of use, the design process, the role of design, user information feedback, etc. Other issues, such as organisational structures and design policies were reviewed at a later stage, when they were found to be important to the progression of the case studies. Chapter 2 contains a part of the result of efforts to meet objectives 3 and 4 above from the literature. The main body of the research adds to the little that was found in the literature search.

3.4 Questionnaire surveys and interviews

A survey involves gathering information from a sample of individuals. Traditionally, surveys are seen to embody research that is representative, that is generalizable, that favours a quantitative approach. This present research took on an exploratory route because no similar research was found in the particular area of the design process relating to customers' opinions and feedback between actual users and designers within the design process. The exploratory nature of the research, which included questionnaire surveys with patients and manufacturers, and interviews with hospital staff and manufacturers, was

needed to take a broad look at the many phenomena under the design process in order to ‘develop ideas’ (Yin, 1994) and to ascertain the relevant variables for the further case studies with manufacturers (Dixon, Bouma and Atkinson, 1992).

The initial aims of the survey research were as follows;

1. To identify and understand clearly the various problems experienced by users of home-based health-care equipment.
2. In particular, to identify problems associated with operational use.
3. To identify formal procedures currently used for the design and development of home-based health-care equipment.
4. To identify to what extent, if any, companies obtain customers’ opinions.
5. To identify how companies convert these opinions into design specifications.
6. To follow the course of design specifications into the actual refinement of product function, etc.

3.4.1 Questionnaire surveys

During the initial stage of the research, it was decided that some information had to be obtained from hospital patients who use medical equipment in hospital and at home, and from manufacturers who make products for them. A questionnaire was considered a suitable method of data collection for the first step.

Questionnaires were carefully formulated to provide: 1. Suitability in the context of the research problem situation. 2. Technical objectivity and relevance. 3. Appropriate questions in plain English. 4. A question format to encourage response (Cohen and Manion, 1994).

The questionnaires for patients were pilot tested and refined, as appropriate, within the times and actual resources available. Questionnaire design and the testing of the questionnaire for this research are described in the following sections. The questionnaires were designed to cover two areas, user groups and company groups. The questions asked were kept simple and were split into various areas, as described in the following section.

3.4.1.1 Questionnaire design for patients

One type of information required from this study was a basic understanding of the problems experienced by users of home-based health-care equipment; in particular, to

identify problems associated with operational controls, i.e. the operational control interface between the person and the equipment.

It was a requirement that the Ethics Committee had to be approached for approval of the questionnaire before it could be given to patients. During that initial approach the author was instructed that for confidential reasons, no personal information about the patient could be requested. So the questionnaire design did exclude patients' personal details such as their names or address, or information about housing, education, finance, age, gender, family circumstances, etc. It was observed that some useful aspects would not be allowed in the enquiry for imposed ethical reasons.

Langrish and Greensides (1996) suggested that some personal information related to those confidential matters might be obtained from each unit of a hospital, but they thought such information would probably be of little relevance to this research. However, many aspects relating to patient capability might relate to education and personal circumstances which could be valuable to the designer but would be unavailable for this study.

The patient questionnaire was developed to achieve the following six objectives.

- To identify:
1. Treatment and equipment types used.
 2. The nature of equipment user training.
 3. Opinions about benefits of use.
 4. Opinions about problems of use.
 5. Opinions about availability/ loan/ ownership.
 6. Opinions about any possible improvements.

Greensides (1996) suggested that the questions should be developed so as not to require demanding responses for the patient, in other words, answers that are difficult for a patient to produce quickly and which would perhaps be difficult for the researcher to process subsequently. Questionnaires should have a clearly thought-out purpose and a structure, which invite enthusiastic support from the patient. Most answers should be anticipated by the respondent and some free comment could be invited at the end.

The above six question areas were then further developed into the 22 questions as the response to the initial pilot question scheme. Table 3-1 shows the subdivision of the questions in relation to the 6 areas of investigation proposed.

Table 3-1. Objectives and questions

O1. To identify treatment and equipment types used.		
1. What types of medical equipment / health-care equipment are you using? Please use product names & types		
2. How long have you been using this equipment? (<i>please tick</i>)	less than 3months 6months-1year	3-6months 1-3years over 3years
3. Do you have any other hospital equipment and home use equipment, related to the same treatment?	Yes	No
4. If yes to 3. Please give equipment names & types		
O2. To identify the nature of equipment user training.		
5. Have you ever received training before using this equipment?	Yes	No
6. If yes to 5. How long were you trained? (<i>please tick</i>)	less than 1 hour 1 month	1 day 1 week over 1 month
7. When you first used this equipment, how did you feel about it?	0%(Nervous) 100%(Safe) <div style="display: flex; justify-content: space-around; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>	
O3. To identify opinions about benefits of use.		
8. What are the benefits of using this product at home?	convenience saving time safety saving travel others (<i>please specify</i>)_____.	
9. What is the most pleasing feature of your equipment?		
O4. To identify opinions about problems of use.		
10. When you first used this equipment, did you have problems with any of the following?	set up control maintenance (using, cleaning) or others (<i>please specify</i>)_____.	
11. How did you overcome these problems?		
12. What is the most frustrating and annoying feature of your equipment?		
O5. To identify opinions about availability/ loan/ ownership.		
13. Is equipment always available when you need it?	Yes	No
14. If not always available, would you have preferred to buy it yourself?	Yes	No
15. Do you know of any different (or better) equipment?	Yes	No
16. If yes to 15. Please give product names & types		
17. If yes to 15. What do you consider is better about this equipment in comparison with what you are currently using?		
18. Who purchased the equipment? (<i>please tick</i>)	yourself hospital others (<i>please specify</i>)_____.	
O6. To identify opinions about any possible improvements.		
19. Do you think there is scope for more home-care treatments with suitable equipment and back up?	Yes	No
20. If yes to 19. Can you suggest any examples?		
21. Could your equipment be improved & how?		
22. Is there anything more you would like to say about the equipment you use?		

Finally, the layout of the questionnaire as shown below Table 3-2, was designed to stay within the parameters of simplicity and user-friendliness.

Table 3-2. Patient questionnaire (1st version)

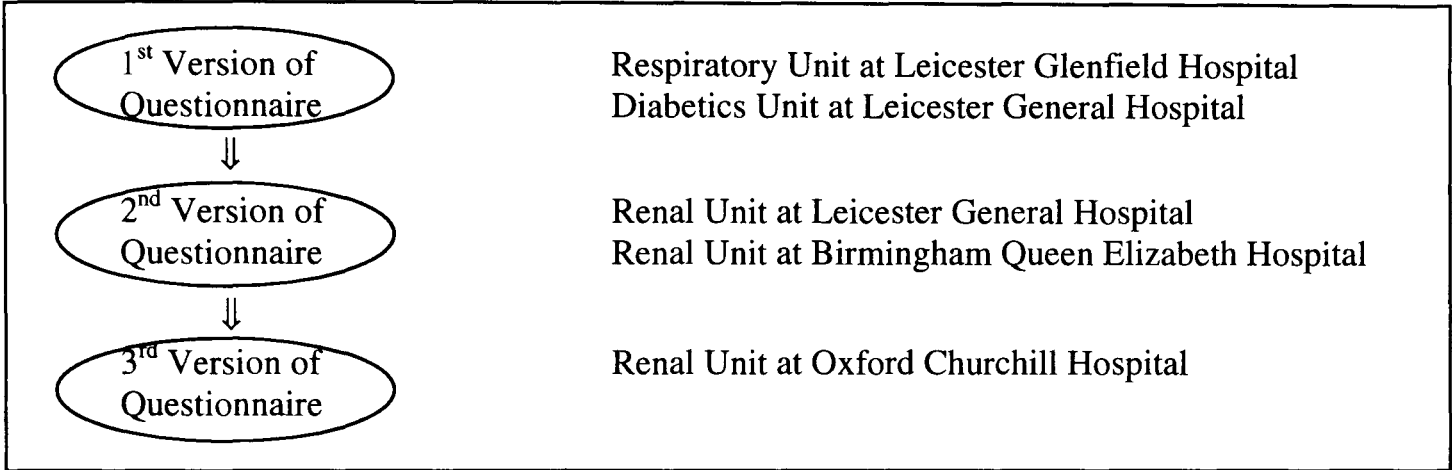
1. What types of medical equipment / health-care equipment are you using? Please use product names & types		
2. How long have you been using this equipment? (<i>please tick</i>)	less than 3months 6months-1year	3-6months 1-3years over 3years
3. Have you ever received training before using this equipment?	Yes	No
4. If yes to 3. How long were you trained? (<i>please tick</i>)	less than 1 hour 1 month	1 day over 1 month 1 week
5. When you first used this equipment, how did you feel about it?	0%(Nervous) 100%(Safe) <div style="display: flex; justify-content: space-between; width: 100%;"> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>	
6. When you first used this equipment, did you have problems with any of the following?	set up control maintenance (using, cleaning) or others (<i>please specify</i>) _____.	
7. How did you overcome these problems?		
8. Who purchased the equipment? (<i>please tick</i>)	yourself hospital others (<i>please specify</i>) _____.	
9. Is equipment always available when you need it?	Yes	No
10. If not always available, would you have preferred to buy it yourself?	Yes	No
11. Do you know of any different (or better) equipment?	Yes	No
12. If yes to 11. Please give product names & types		
13. If yes to 11. What do you consider is better about this equipment in comparison with what you are currently using?		
14. What are the benefits of using this product at home?	convenience saving time safety saving travel others (<i>please specify</i>) _____.	
15. Do you have any other hospital equipment and home use equipment, related to the same treatment?	Yes	No
16. If yes to 15. Please give equipment names & types		
17. Do you think there is scope for more home-care treatments with suitable equipment and back up?	Yes	No
18. If yes to 17. Can you suggest any examples?		
19. What is the most frustrating and annoying feature of your equipment?		
20. What is the most pleasing feature of your equipment?		
21. Could your equipment be improved & how?		
22. Is there anything more you would like to say about the equipment you use?		

3.4.1.2 Pilot testing of the user questionnaire

Three drafts of the patient questionnaires were developed. Figure 3-2 shows the progression of the three drafts of the questionnaire and the hospital units which provided comments allowing draft revisions.

The first draft of the proposed questionnaire was shown to the director of studies, and he second supervisor at De Montfort University and hospital professionals for their comments and opinions. It was then edited and sent to various respondents for pilot testing. Initial studies were conducted in three units at two hospitals before the first revised versions of the questionnaires were made ready for circulation. The reason for undertaking this pilot testing phase for the survey questionnaire, was to evaluate the effectiveness of instructions, questions and the response systems, to screen out vagueness, ambiguity and local progress of the questions.

Figure 3-2. Versions of patients questionnaires



Most comments were positive and constructive. The suggestions of the academic and medical professionals were very valuable and resulted in positive revisions of the original questions for the pilot study. The original questionnaire (1st version) was carried out with patients at the Respiratory Unit at Leicester Glenfield Hospital and at the Diabetics Unit at Leicester General Hospital. However, some comments were also received from the Renal Unit at Leicester General Hospital. The comments from the Renal Unit were as follows;

The following were comments on specific questions in the second version questionnaire.

- Questions number 3 - all haemo dialysis patients receive training.
- 4 - the time scales need to be longer, may be up to 6 months.
- 5 - nervous and safe are not comparable.
- 6 - first used equipment at home or supervised in hospital.
 What does control mean?
- 8 - all equipment is supplied and maintained by the hospital.
- 9 - not applicable.
- 10 - not an option.

Therefore, the original questionnaire was modified to take account of the comments above and then a second version was made (see Table 3-3).

Table 3-3. Patient questionnaire (2nd version)

1. What types of medical equipment / health-care equipment are you using? Please use product names & types		
2. How long have you been using this equipment? (<i>please tick</i>)	less than 3months 3-6months 6months-1year 1-3years over 3years	
3. How long have you received training before using this equipment? (<i>please tick</i>)	1 day 1 week 1 month less than 3months 3-6months over 6months	
4. When you first used this equipment, how did you feel about it?	0% Unsafe(Nervous) 100% Safe <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
5. When you first used this equipment at home, did you have problems with any of the following?	set up (before use) control (adjustments in use) maintenance (before & after use, cleaning, storage, etc.) other things (<i>please specify</i>)_____	
6. How did you overcome these problems?		
7. Do you know of any different (or better) equipment?	Yes	No
8. If yes to 7. Please give product names & types		
9. If yes to 7. What do you consider is better about this equipment in comparison with what you are currently using?		
10. What are the benefits of using this product at home?	convenience saving time safety saving travel other (<i>please specify</i>)_____	
11. Do you have any other hospital equipment and home use equipment, related to the same treatment?	Yes	No
12. If yes to 11. Please give equipment names & what it is used for.		
13. Do you think there is need for any other home-care treatments, if suitable equipment and help is provided?	Yes	No
14. If yes to 13. Can you suggest any examples?		
15. What is the most frustrating feature of your equipment?		
16. What is the most pleasing feature of your equipment?		
17. Could your equipment be improved & how?		
18. Is there anything more you would like to say about the equipment you use?		

The second version of the questionnaire was accepted at the Renal Unit at Leicester General Hospital and the Renal Unit, Birmingham Queen Elizabeth Hospital but some comments were added by the Research Ethics Committee at Oxford Radcliffe Hospital who requested the addition of: -

'If you are experiencing considerable problems using your equipment, please consult your doctor'.

'Although findings will be made public, individuals will not be named, and any data collected will be confidential'.

Finally, a third version was produced.

3.4.1.3 Questionnaire design for manufacturers

A second, different questionnaire was designed for companies to obtain information about how the company obtains customers opinions and converts these opinions into design specifications. The survey aimed to gather basic information from the industry in order to roughly ascertain the design process. Although the questionnaire was short (3 sides of A4 paper, see Table 3-4), a telephone follow-up was needed to achieve the company survey. The company questionnaire was addressed to the managing director of the company or head of design department or person who is in charge of design matters, as appropriate to the size of the company.

Table 3-4. Manufacturers' questionnaire

1. What types of medical equipment / health-care equipment do you supply for professional use? Please use equipment names & types.			
2. Does your organisation supply hospital equipment and home use equipment, nominally for the same treatment?	Yes	No	
3. If yes to 2. Please give equipment names & types & please supply technical sales leaflets (if available).			
4. Does home treatment equipment effectively reach more patients than hospital treatments of same or similar types?	Equipment name & types	Yes	No
5. Do you think there is scope for more home-care treatments with suitable equipment and back up?	Yes	No	
6. If yes to 5. Can you suggest any examples?			
7. Do you have your own design team?	Yes	No	
8. If yes to 7. What is its professional make up?	industrial designer	technician	
	production	engineer	ergonomist etc.
9. If no to 7. Who designs the equipment you produce?			
10. Have you introduced any new products or product modifications during the last 2 years?	Yes	No	
11. If yes to 10. How many?			
12. Do you produce your own new product design briefs?	Yes	No	
13. Do users' opinions feature in the product change brief?	Yes	No	
14. If yes to 13. How do you obtain their opinions?	customer enquires	sales department	
	questionnaires	customer homes	etc.
15. Do you think the total market for home-based health-care equipment is expanding?	Yes	No	
16. Are you prepared be reveal any information about your own market share?	Yes	No	
17. If yes to 16. Please state.			
18. Are there any comments you would like to add?			

3.4.2 Patient survey

Two companies, Gambro and Drager Ltd., recommended two hospitals which were the Renal Unit at Leicester General Hospital and the Respiratory Unit at Leicester Glenfield Hospital for the patients' survey. One hospital, the Diabetics Unit at Leicester General Hospital, was recommended by Prof. Tom Cassidy, an advisor for this research, of De Montfort University. Two more hospitals were added during the Renal Unit survey at Leicester General Hospital; these were Birmingham Queen Elizabeth Hospital and Oxford Churchill Hospital. The latter was recommended by Ms. Ann Keogh of the Renal Unit at Leicester General Hospital. For the purpose of the user survey, Ethics Committee approval was required and each region had different applications

3.4.2.1 Ethics Committees

Four applications were required from each hospital and each application was submitted to three Ethics Committees, respectively for the Leicestershire, Birminghamshire and Oxfordshire areas. Each application form had four requirements, namely, a detailed protocol, details of any questionnaires used, a proposed consent form and a patient information leaflet.

The ethics committee in considering an application for ethical approval, bears in mind the Royal College of Physicians guideline that 'badly planned, poorly designed research that causes inconvenience to subjects and may carry risk without producing useful or valid results, is unethical' (Quoted from Leicestershire Health Authority, 1996).

3.4.2.1.1 Leicestershire Ethics Committee

Two applications with protocol (see Appendix 1), user information (see Appendix 2) and the proposed questionnaire were submitted. The result of those applications were audited by the Leicestershire Ethics Committee. The Leicestershire Ethics Committee felt that this was sufficient audit and that therefore, ethics committee approval was not required but some clarification was required. After that, however, a letter was sent by the Leicestershire Ethics Committee to the Ethics Committee at Leicester General Hospital, Leicester Glenfield and the author. This letter suggested that if this study needed to visit patients or look at pieces of equipment other than those mentioned in the original application the author needed to communicate with them again in advance of extending the study.

3.4.2.1.1.1 Leicester General Hospital

As part of the approval procedure an interview was required by Dr. Seare, Research Manager at the Ethics Committee at Leicester General Hospital. The result of the interview was that the Renal Unit could not offer a user survey because other research was already being carried out with other researchers. However, an in-depth interview with three patients was promised. Other user surveys with Diabetics Unit at the same hospital were carried out after that.

Diabetics Unit

The questionnaire survey was carried out two days a week during the consulting days which were offered by Dr. Burden, consultant at the Diabetics Unit. Dr. Burden suggested that a waiting room would be the best place to have a questionnaire survey. The questionnaires were filled in by the respondents in the presence of the researcher.

This allowed for interview questions to be added. The Diabetics Unit study was planned for 4 weeks but it required two more weeks, since it was found that many patients were of Asian origin and there was a communication problem, even though many they had come with family or friends to help them to interpret during consultations. According to Dr. Burden this communication problem between consultants and many Asian people is common to other hospitals in the Leicester area. After that, the results were analysed and, at the same time company research was also being carried out. The final results of the patient questionnaire were discussed a few months later and some comments were added by Dr. Burden and other staff.

Renal Unit

In-depth interviews with three patients took place at the Renal Unit. However, the author felt that the information given by patients was too variable and general standardised information was necessary.

An appointment was made with Dr. Feehally, consultant at the Renal Unit. The user survey was permitted by Dr. Feehally after explanation of the research by the author. In the meantime, the questionnaire was sent to Ms. Ann Keogh. She suggested several things that could be more applicable to the Renal Unit. The questionnaire was modified on her suggestions, as can be seen in Table 3-3.

Dr. Feehally asked the author to provide 40 copies of the questionnaire and 40 stamped self-addressed envelopes. A covering letter was later received by him saying that the questionnaire had gone to 14 peritoneal dialysis patients and 21 kidney dialysis patients. The completed questionnaires were received after six weeks. The results were analysed and in the meantime the Birmingham and Oxford user surveys were also proceeding. A final approach to Dr. Feehally was made after finishing the Renal Unit survey. The final results were discussed and some comments were added by Dr. Feehally and the other members of staff.

3.4.2.1.2 Leicester Glenfield Hospital

An interview was undertaken with Dr. Adcock of the Ethics Committee at Leicester Glenfield Hospital. Mr. D. Vara, of the Respiratory Unit was informed of ethics approval and the research was carried out following that approval.

The questionnaire survey was carried out twice a week for 6 weeks until 30 questionnaire surveys had been obtained. The study at the Respiratory Unit involved the questionnaire survey together with some interview questions. 30 patient questionnaires were completed and analysed. Finally, the results were discussed and some comments were added by Mr. Vara and other staff.

3.4.2.1.2 Birminghamshire Ethics Committee

A letter with protocol, questionnaire and user information were sent to Mrs. Marie Hamilton, Senior Nurse Manager of the Renal Unit at Queen Elizabeth Hospital. The author telephoned and asked for her help in this study. She agreed to help, but ethical approval was required.

An application and information were received from Birmingham Ethics Committee and a letter was sent to Dr. Jubb, Chairman of the Local Research Ethics Committee, with an explanation of the study. A reply was received after two weeks with some suggestions. Following that, a letter with brief protocol, questionnaire and user information was sent to Dr. Jubb. Finally, formal chairman's approval was sent to the author indicating that permission had been given to continue with this investigation.

An appointment was made with Ms. Hamilton to deliver 30 questionnaires with a

covering letter and prepaid envelopes. Ms. Duncan, Committee Nurse, did not hand these on to patients for a month, but after the author's prompt, this was done. 14 patient questionnaires were received and analysed. Finally, the results were discussed and some comments were added by Mrs. Hamilton and other staff.

3.4.2.1.3 Oxfordshire Ethics Committee

A letter with an explanation of the study was sent to Miss Bevis, Assistant Administrator of the Ethics Committee at Oxford Radcliff Hospital.

Miss Bevis' reply indicated that a full application form was required. Following a discussion with Prof. Tom Cassidy, an advisor for this research, a phone call was made to Miss Bevis to solve the issue of legal indemnity for the project. However, a full proposal using the application form needed to be made. Although another letter was sent to Mr. Lindsay Combes, Chairman of the Research Ethics Committee, the result was the same. Full application was made and sent to the Oxford Churchill Hospital to be signed by Dr. Winearls, Clinical Director, and Mrs Hamilton, Senior Nurse Manager.

There was a delay in that, although Dr. Winearls signed, Mrs Hamilton did not sign immediately, because of her work which involved travelling overseas. Several appointments to meet her were cancelled. Finally a meeting with her was achieved and she signed. The application was sent to the Oxford Ethics Committee. Four months were involved applying for Ethics approval, before agreement was finally received.

During the hospital user survey with Oxford Churchill Hospital, the information letter accompanying the questionnaire was given to the committee with permission to use it as an example of good practice (see Appendix 3).

The findings of the questionnaire surveys are presented in Chapter 4. The answers to the open ended questions were subjected to content analysis, and concepts based on groups of responses were recorded. An open-ended form of content analysis holds much potential as an exploratory generative technique (Scherl and Smithson, 1987). The use of content analysis as a technique in this research is to identify appropriate units of analysis, which may include single word, a sentence and a paragraph (Cohen and Manion, 1994). These results partly satisfy Aim 2 of the study, which was to discover the benefits and deficiencies to the user of using home-based health-care equipment.

3.4.3 Interviews

Burgess (1994) stated that the interview is the opportunity for the researcher to probe deeply to uncover new clues, open up new dimensions of a problem and to secure vivid, accurate inclusive accounts that are based on personal experience.

According to Cohen and Manion (1994) research interviews can be outlined in four types, namely, the structured interview, the unstructured interview, the non-directive interview and the focused interview. Each of them has its advantages and disadvantages. The focused interview differs from other types of research interview in certain respects that it is the prior analysis by the researcher of the situation in which subjects have been involved. The actual interview is focused on the subjective experiences of the persons who have been exposed to the situation. Therefore, for this research, the focused interview was used to achieve the objectives for the hospital staff surveys.

Miller (1983) claimed that the semi-structured interview is defined as focusing on a core of standard; questions or topics, with other questions generated from the interviewee's response. It provides advantages in which all individuals' responses can be compared to the core questions, and other issues, spontaneously raised by the interviewee can be taken account of. Miller (1983) further suggested that the semi-structured interview provides enough freedom for interviewees to steer the conversation and allows them to express their opinions completely, which enables the researcher to explore the field for developing ideas and confirming the influencing factors for further case studies. Therefore, the semi-structured interview was considered the most appropriate for the manufacturers' interviews.

A pilot interview was conducted with Dr. John Langrish, Director of Studies, Manchester Metropolitan University and Christopher Greensides, Senior Tutor at De Montfort University, who has much experience in design practice. For the purpose of obtaining additional information for this research, focused interviews and semi-structured interviews were designed and conducted to allow further identification of the key factors. These interviews allowed close contact between subject matter and the researcher, which was useful in this area, where the theory has not yet been well developed. These methods were applied for the studies of hospital staff and manufacturers.

3.4.3.1 *Design and construction of interviews*

‘Face-to-face’ personal interview techniques were used for hospital staff. The structure of the interview questions for hospital staff was primarily to achieve the following objectives.

1. To identify trends and types of home-based health-care equipment.
2. To explore the nature of user training for home-based health-care equipment.
3. To gather opinions about control mechanisms.
4. To identify opinions about problems of use.
5. To explore opinions about any possible improvements.

It was decided that a self-fill questionnaire method should be applied to the patients’ survey at the diabetics unit and the respiratory unit. This method allows respondents to write their responses in the space provided in the questionnaire forms. It was interesting and proved beneficial that the questionnaire survey and the interview methods used in the data collection complemented each other. These have helped the author to strengthen the findings for this research.

The focused interview was used to achieve the above objectives with a conversational style focusing on respondent experience, instead of having set questions. Another part of the study was conducted by questionnaire and semi-structured interview which offered fairly structured sets of questions providing the interviewees with a guide to follow when exploring their thoughts about their past experiences. This was used for manufacturers as a follow-up from the questionnaire survey of manufacturers.

The questions for exploratory interview with manufactures were: -

1. How many new products has your company developed and sold in the past few years?
2. Who often proposes the ideas for change or development?
3. If the idea was proposed by people outside the design department, who were the people? Is there any customer opinions’ input?
4. Who takes decisions concerning whether proposed ideas should be carried out or not?
5. Do you have a formal committee to make such decisions?
6. Do you have a design brief for the design department? What is the form of the design brief?
7. How does design fit into the overall management system?

8. Can you recommend some products as examples of product change which were initiated by customers' opinion input?

After products had been chosen, the following questions were asked of each selected product:

1. What were the reasons for change or modification?
2. Who proposed the idea which caused the product changes?
3. What was the form of the proposal?
4. Who was the person or group that decided to commit resources for the product modification?
5. What was the design brief?
6. Who prepared it?
7. How does your company obtain customers' opinions?
8. How does your company convert customers' opinions into design specifications?
9. What are the formal procedures for the design and development of home-based health-care equipment?

3.4.3.2 Conducting exploratory interviews

Six hospitals, one university and thirteen companies were involved in the exploratory interviews. A total of twenty-five persons participated in the company interviews, one person participated from a university and thirteen persons participated in the hospital interviews.

The findings of the interview surveys are presented in Chapters 5 and 7. These results partly satisfy Aim 2 of the study which was to discover the benefits and deficiencies to the user of using home-based health-care equipment and Aim 3 which was to identify deficiencies in the design process of home-based health-care equipment. However, the manufacturers' survey, the process of approaching organisations for interview and how case studies were carried out are discussed Sections 3.5 and 3.6.

3.5 Criteria for the choice of case studies and the process of approaching organisations

3.5.1. Criteria for the choice of case studies

As a research method, case studies were planned to illustrate various real examples of mechanisms and procedures that were being used in practice. This was to expand upon existing knowledge, and to show examples of real life systems and whether they appeared to be correct or less than satisfactory.

The case studies specifically aimed to identify deficiencies in the design process of home-based health-care equipment in order to identify how manufacturers convert users' opinions into the design specification. Various other aspects of design development were also presented for discussion.

At the planning stage of this part of the research, it was intended that the case studies should provide information over three main areas, namely, the case studies should link manufacturers who design and produce the equipment with people who are involved with purchase of the equipment, secondly, with people who receive the treatment, and finally, how information transfers back through the process to the manufacturers' new product design team.

The main criteria for selecting manufacturers to approach were -

1. That the manufacturers should be willing and able to participate
2. That the products manufactured and discussed should ideally be the same as those being referred to in other parts of this study (Note that some products referred to in the early part of this study, for example, the AK 100 haemo dialysis machine had undergone design modification by the time the Gambro case study took place).
3. To select different types of home-based health-care equipment manufacturers. It was hoped that the study could cover a variety of product manufactures according to the definition of home-based health-care equipment categories.
4. To restrict selection to home-based health-care equipment manufacturers in relation to what the user surveys anticipated.
5. Selection was based on a deduction about the firms' willingness to co-operate.

In fact, as it turned out, the process of obtaining co-operation from manufacturers was full of problems as described in the next section.

3.5.2 Access to organisations

According to Zainuddin (1992), finding firms which are suitable for case studies and are willing to co-operate has been claimed to be a very hard task. Similarly, this research involved great efforts to gain co-operation from suitable firms.

The first step was to select home-based health-care equipment manufacturers for information gathering whose major tasks are product design, and of those, the manufacturers who had an in-house design team.

The initial aims of the study of home-based health-care equipment manufacturers were as follows:

1. To identify how, if at all, the company obtains customers' opinions.
2. To identify how the company converts these opinions into design specifications.
3. To identify formal procedures for the design and development of home-based health-care equipment

Unfortunately, there were no directly related information sources available for selecting companies since, home-based health-care equipment is relatively new to the market.

The firms were selected from three literature sources:

1. Kompass 1993/94, Volume I and Volume II. Volume I provided details of some 40,000 different products and services offered by British Industrial Companies in different product groups. Medical equipment was under category 38, life saving equipment was under category 49, hospital equipment & supplies were under category 66-67 and medical care was under category 87. After appropriate firms had been picked out in these four categories, the information was obtained from Volume II.
2. Healthcare Equipment International provides information on markets, companies and statistics in 1989. A total of 121 UK companies were found.
3. ABHI (Association of British Healthcare Industry) Directory 1994 provided 120 companies. Different products and services offered by British Industrial Companies were listed in different classifications. Manufacturers' products and services were under classification A.

These three information sources provided specific practical and statistical information about companies, such as address, telephone numbers, names of directors, employees, turnover, product groups, etc. Companies more related to home-based health-care equipment manufacturers were then selected from these firms.

The selection from Kompass 1993/94, Healthcare Equipment International: markets, companies, statistics 1989 and the ABHI (Association of British Healthcare Industry) Directory 1994 encountered difficulty due to no information being available about the nature of the companys' products, which was recognised as a main criterion for assessing if the organisation had a high dependency on industrial designers in the product design process.

During the selection of the firms, the ideal person for interviews for the purposes of this research was considered to be the person who was in charge of product development in that firm. Since this researcher did not know these persons nor was able to be introduced to them by mutual contacts, direct phone contact was considered the only way to find out the names of product development managers. However, communicating with telephone operators was very time consuming and frustrating especially in the large firms which, for example, could have many people in charge of product development on different levels or in different products. In some firms, the department in charge of the product development could be referred to by different names, for example, an R&D director or a marketing director. Many explanations were needed to get through to the right person. Nevertheless, eventually, the person who needed to be contacted in these firms was identified by name.

210 companies were selected, and letters and questionnaires were sent to each company. Introductory letters explaining the aims of the investigation were sent to these people asking for co-operation for information and further assistance. From the initial number, 114 companies sent some information. Of these, 41 companies were identified as home-based health-care manufacturers and 73 companies were not. Of the remaining 96, 25 companies no longer existed or had changed address and 71 companies simply did not respond.

Of the 41 companies, identified as home-based health-care manufacturers, only 5 were actually interviewed. There were various reasons why the remaining firms were reluctant to be interviewed. For example, NomeQ Ltd. was busy at that moment and asked to contact Ketter Ltd., but Ketter Ltd. felt such requests should be directed to other companies. Novo Nordisk Ltd. no longer manufactured and supplied any health-care equipment. After exploratory phone calls or letters, some companies were found not to be involved in production and others had no time to spare to assist, etc. The following list comprises the names of the people and the firms who agreed to interviews.

1. Arjo Ltd.	Managing Director	Mr. Somerton
2. A & M Hearing Ltd.	Manager	Mr. Gibbs
3. Edale Instruments	Director	Mr. A. Hodgson
4. Johnson & Johnson Medical Ltd.	Marketing Manager	Mr. Steven Apkinson
5. Medex Medical Ltd.	Product Specialist	Ms. Louise Fountaine

Interviews took place with the 5 companies but, only one company, Arjo Ltd., was suitable for a case study. Although A & M Hearing Ltd. manufactures some products in the UK, most of its products are designed in the USA, Denmark and Switzerland. Edale Instruments developed only one product about 10 years ago and not much information was available. Research could not be carried out with Johnson & Johnson Medical Ltd. because of confidential reasons. Medex Medical Ltd. manufactures all its products in the USA and they only distribute to the UK market. No information was available from these four companies for the purposes of this research.

At this point, with such a small potential sample, another company approach was required. In total, 44 companies were selected from the RSA (The Royal Society for the encouragement of Arts, manufactures & commerce 1996) conference leaflet. The organisations selected were initially approached by letter with an explanation of the aims of the investigation and questionnaires. Before sending this letter, the key informers for interviews were confirmed through phone calls to the company receptionist to gain the correct person's name and position in the organisation. Afterwards, telephone calls were made to confirm approval to carry out an interview.

A total of seventeen responses by letters and fax were received. Among these, nine organisations agreed to support this investigation, whereas thirty-five companies responded negatively. Those companies which refused access did so for a variety of reasons, as follows:

- 1) Individuals had no time to spare to assist with an interview because of the work load
- 2) There was the confidential nature of the current design projects
- 3) The majority of current work was other than in the field of product design
- 4) Minimal or no product design work was undertaken in their company
- 5) The research projects were not really applicable to their business, following a restructuring of their company.

In total, twenty-two companies, five companies from first information gathering and seventeen companies from the second information gathering were involved with the questionnaire survey, which is presented in Chapter 6. Of these twenty-two companies, only thirteen organisations contacted agreed to take part in an initial interview and one, Medic-Aid Ltd., agreed to send information and questionnaires by post.

The following table provides details of the companies which took part, with the name and position held of the staff agreeing to take part in the interviews.

Table 3-5. Companies and interviewees

	COMPANY	NAME	POSITION
1.	A & M Hearing Ltd.	Mr. Gibbs	Manager
2.	Arjo Ltd.	Mr. Somerton	Managing Director
3.	Baxter Healthcare Ltd.	Ms. G. Stansfield	APD Manager
4.	Boehringer Mannheim UK Ltd.	Mr. Tom Glanfield	Technical Specialist
5.	Clement Clarke International Ltd.	Mr. P. Guy	Product Manager
6	Drager Medical Ltd.	Mr. N. Pattinson	Manager
7.	EMS (Electro Medical Supplies) Ltd.	Mr. Wilton	Director
8.	Gambro	Mr. Phillip Middleton	Manager
9.	Gimson Stairlifts Ltd.	Mr. Blackburn	Manager
10.	Huntleigh Nesbit Evans (HNE) Technology plc Group	Dr. Steve Cook	Technical Managing Director
11.	Medi Sense Inc	Dr. Sanghera	Technical Director
12.	Medic-Aid Ltd	Ms. Katie Dexter	Product Manager
13.	Novamedix Ltd	Mr. Ian Brown	Marketing Director
14.	Oxford Instruments Ltd.	Ms.Pauline Hobday	Director of Strategic Planning

Generally speaking, a number of tactics have been developed in order to overcome problems of access to organisations for research. A number of researchers have mentioned that this is becoming more difficult partly because companies are being deluged by requests for research (Buchanan et al., 1988; Brown et al., 1976; Platt, 1976), and partly because the research is related to the issue of confidentiality of the company (Zainuddin, 1992).

To overcome these problems, Buchanan et al. (1988) suggested an opportunistic approach through friends and relatives to contact organisations. The co-operation of one company, HNE Technology plc Group, went through introductions from friends and another, Oxford Instruments Ltd., was recommended by interviewees. Another issue worthy of mention was that the researcher was required by three companies, namely, Johnson & Johnson Ltd., HNE Technology plc Group and Arjo Ltd., to sign an agreement to ensure that the information gained was not too commercially sensitive. These company approaches of signing an agreement overcame the problem of being denied access due to confidentiality.

3.6 Case studies

Interviews and documentary collection were carried out with thirteen organisations. Among those companies, three case studies were conducted by the researcher visiting for one day or two days in the design field to obtain data about the organisation, views and opinions about the design process and the input of customers' opinion, etc. As a result of pilot interviews, it was decided that 3 companies were most suitable for further case studies. Manufacturer interview results are presented in Chapter 7.

The next section describes how the case studies were conducted.

3.6.1 Conducting case studies

The companies involved with case studies are HNE Technology plc Group (Huntleigh Healthcare, Huntleigh Diagnostic, and Huntleigh Kinetics), Gambro and Arjo Ltd. All information from the case studies was collected by methods which were carried out as follows:

- 1) Interviews were carried out with the people involved in the product design and design process, including designers, non-designers or managers.
- 2) Semi-structured interviews were used but also an 'unstructured conversation' was used when some interesting or conflicting issues were involved.
- 3) Documentary information, such as design briefs, project reports and company brochures, were viewed and collected if possible.

Interviews were conducted with different people from different roles and positions which provided different perceptions and opinions which might draw up the phenomena of the product design and design process. The interview questions in the case studies were basically the same as those in the interview survey of thirteen companies. During interviews, further questions were added as considered necessary to discover more interesting issues in each case.

The 'unstructured conversations' were carried out not only to discover some sensitive issues, such as conflict and problems in the design process, but also to uncover the inside meanings of some interesting issues such as legislation, etc. The persons in the participating organisations were more accessible after the researcher had stayed one or two days and they had become more familiar with each other. Unstructured conversations, which could provide an effective way to collect sensitive information, seemed to be one of the major merits of the field research.

Interviews with other people relating to design and the collecting of documentation were adopted in order to enhance the data collection. According to Yin (1994), documentary information is relevant to every case study topic. Within the context of this research, documents are helpful regarding the company brief, design projects, design report and design brief, etc., and were collected as fully as possible. This documentation provided evidence and information that the case studies relied very much on, namely, the organisational structure and the design process regarding one specific design project.

The author's experience as a designer was of benefit to the design research, thereby being able to find out what questions were of importance to design or of interest to designers, and to ask the right questions while conducting a semi-structured interview. Thus, sensitive questions were able to be asked and some confidential data were obtained. The author's design knowledge and experience also enhanced his sensitivity to and recognition of the collected data during the data evaluation and analysis stages.

The results of the interviews and the materials from the case studies' collection were written up as case-study reports. The reports were sent back by mail to the key informers who had contributed the most information for the cases. This stage is not just a matter of checking the reports. It often produces extra important information (Langrish, 1993). In relation to this expectation, comment sheets were enclosed with the reports, not only for the purpose of checking the information for accuracy and correction, but also with the expectation to gain further suggestions and comments from the informers.

The final results of the case studies gathered from the three participating organisations and twelve interviewees are described in detail in Chapters 8 to 10. These case studies partly satisfy Aim 3 of this research.

3.7 Analysis and synthesis

The overall results of the study were produced by a combination of qualitative and quantitative approaches which was inspired by 'Grounded Theory' to analyse the surveys and case studies. The idea of grounded theory as first formulated by Glaser and

Strauss (1997) provides a 'comparative method' which looks at the same event or process in different settings. Bryman (1992a) suggests grounded theory as a means of generating theory which is embedded in data and Yin (1993) also states that it is interested in theory-building and not theory-testing.

Thus, Bryman (1992a) pointed out, this approach has some appeal to researchers: 1) it allows theory to emerge from the data, so that it does not lose touch with its empirical referent, 2) it provides a framework for the qualitative researcher to cope with the unstructured complexity of social reality and so render it manageable, and 3) it allows the development of theories and categories which are meaningful to the subjects of the research. It emerges that grounded theory has a certain application when no particular prior theory appears relevant or is explicable (Yin, 1993).

Yin (1993) argued that the analytic strategy is more important than the analytic technique. According to Strauss and Corbin (1990), the analytic procedures of grounded theory are designed to: '1) build rather than only test theory, 2) give the research process the rigor necessary to make the theory 'good' science, 3) help the analyst to break through the biases and assumptions brought to, and that can develop during, the research process, 4) provide the grounding, build the density, and develop the sensitivity and integration needed to generate a rich tightly woven, explanatory theory that closely approximates the reality it represents'.

Grounded Theory was considered as a suitable analytic tool for this study, due to its advantages mentioned above.

It has been suggested that the quality of data analysis can be enhanced by the use of computers (Conrad and Reinhartz, 1984; Tesch, 1990). Lee and Fielding (1991) stated that the computer made research easier 'to find deviant cases or to extract small but significant pieces of information buried within a larger mass of material'. In this sense, the Microsoft program 'Excell 97' was adopted by this study to assist data analysis.

The final analysis and synthesis fulfil the fourth aim of the study. The discussion and the overall conclusions are presented in Chapter 11, together with suggestions for further research.

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Chapter 4

Patients Surveys

Patients, who use HBHC equipment

CHAPTER 4. PATIENTS SURVEYS

- Patients, who use HBHC equipment

4.1 Introduction

The aim of this chapter is to present the research findings of the patient questionnaire surveys. As discussed in Chapter 3, the questionnaire design focused on a basic understanding of problems experienced by users of home-based health-care equipment. Some useful questions could not be asked because of ethical problems and some of the questions were too technical for patients to answer. Therefore, in addition to the questionnaires, interviews with some staff took place. The results of the staff interviews are presented in the next chapter.

The findings from the patient questionnaires are divided into four different types of equipment used in patients' homes. The first section of this chapter starts with a general discussion of the patient questionnaire findings, Section 4.2. Section 4.3 discusses the *haemo dialysis* user survey. Section 4.4 discusses the *peritoneal dialysis* user survey. Section 4.5 discusses the *diabetic product* user survey. Section 4.6 discusses the *nebulizer* user survey. The final section presents the overall findings of the patient group questionnaire surveys.

4.2 Results of the patient questionnaire surveys

The patient surveys were completed using a questionnaire. The questionnaires were analysed by using a spreadsheet processing software called 'Excel 97'. The respondents were asked both simple optioned questions and also open-ended questions. The answers to the open ended questions were subjected to content analysis (Cohen and Manion, 1994).

The equipment was used by patients in renal units, a respiratory unit and a diabetics unit. This user questionnaire survey involved 133 patient at five units of four hospitals (see Table 4-1).

Table 4-1. Hospitals & respondents

Hospitals	Total patients	Patient responses	Response rate
	(Haemo dialysis + peritoneal dialysis)		
Oxford Churchill Hospital Renal Unit	38+20=58	26+15=41	70.68%
Leicester General Hospital Renal Unit	23+13=36	14+11=25	69.44%
Birmingham Queen Elizabeth Hospital Renal Unit	7+6=13	5+2=7	53.84%
Leicester General Hospital Diabetics Unit		30	
Leicester Glenfield Hospital Respiratory Unit		30	

Since the questionnaire was developed it has been applied at 3 different units at 4 hospitals; but some modifications were incorporated (see page 56). Also in 2 units (Diabetics Unit and Respiratory Unit), the questionnaires were filled in by the respondents in the presence of the researcher. The questionnaire survey was carried out until 30 responses each had been obtained from the Diabetics Unit at Leicester General Hospital and the Respiratory Unit at Leicester Glenfield Hospital (see Table 4-1).

As part of the questionnaire design the general nature of some questions was intended to produce different answers about different treatments.

The answers to the questions were reassembled and analysed in order to address the following six objectives.

- To identify:
- 1. Treatment & equipment types used.
 - 2. The nature of equipment user training.
 - 3. Opinions about benefits of use.
 - 4. Opinions about problems of use.
 - 5. Opinions about availability/ loan/ ownership.
 - 6. Opinions about any possible improvements.

Each of the following sections provides the results of the questionnaire for groups of different equipment users. The sections are preceded by brief explanations of the nature of the equipment.

4.3 Haemo dialysis user survey

This section provides the analysis of a questionnaire survey at 3 hospitals the Renal Unit of Leicester General Hospital, Oxford Churchill Hospital and Birmingham Queen Elizabeth Hospital. Responses were received from 45 haemo dialysis users (see Table 4-2).

Table 4-2. Haemo dialysis respondents

Hospitals	Total haemo dialysis patients	Patient responses	Response rate
Oxford Churchill Hospital Renal Unit	38	26	68.42%
Leicester General Hospital Renal Unit	23	14	60.84%
Birmingham Queen Elizabeth Hospital Renal Unit	7	5	71.42%

4.3.1 Description of equipment

A person who suffers from chronic kidney failure, whose kidneys have virtually ceased to function, can survive with the aid of dialysis treatment. Several treatment options are available for people with kidney failure, sometimes called ‘end stage renal disease’ or ESRD. Care options include kidney dialysis, kidney transplantation, and non-treatment (Baxter International Inc, 1997).

The two most common forms of treatment are haemo dialysis, which is used by 85 percent of all patients, and peritoneal dialysis (Gambro Group Annual Report, 1996). This section discusses haemo dialysis and the next section peritoneal dialysis.

4.3.1.1 The function of a healthy kidney

According to Jangmark (1997) approximately 1,700 litres of blood normally pass through the kidneys every 24 hours. In the kidneys, the blood is distributed into about two million nephrons. The nephron is the kidney’s smallest functional unit; it can independently clean the blood and produce urine. In the nephron, the blood goes first to the glomerulus, a very small round structure of minute blood capillaries.

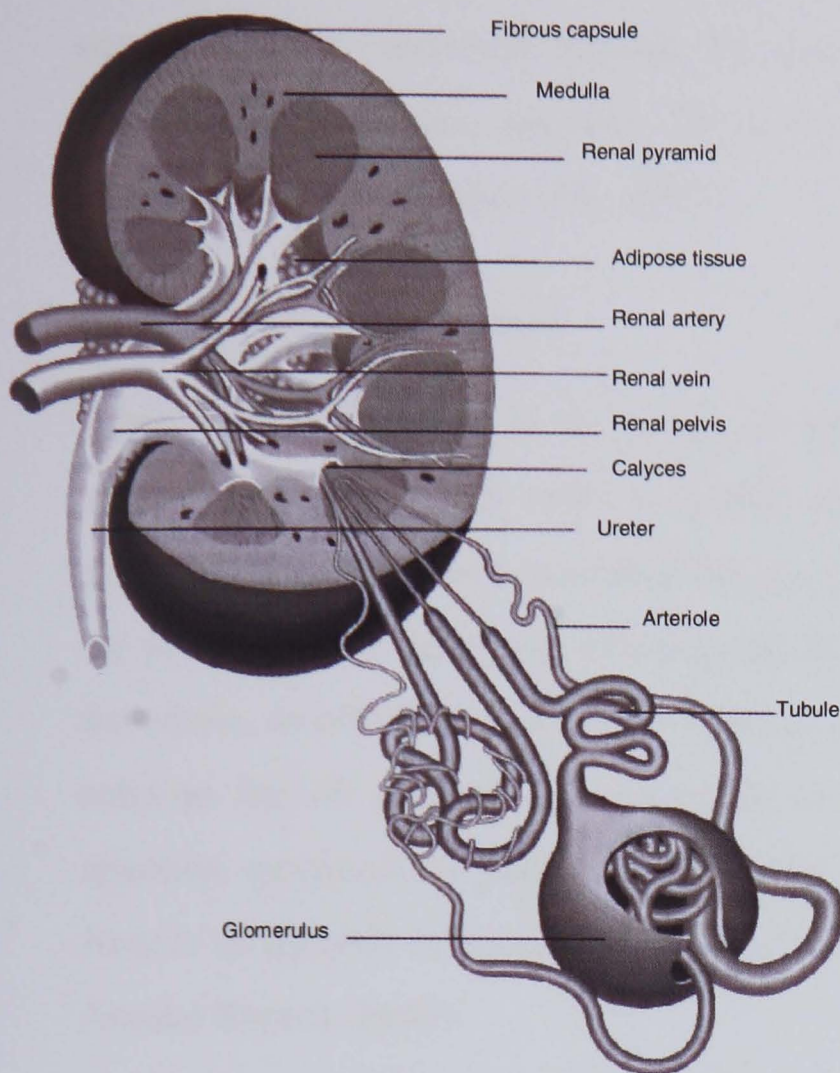


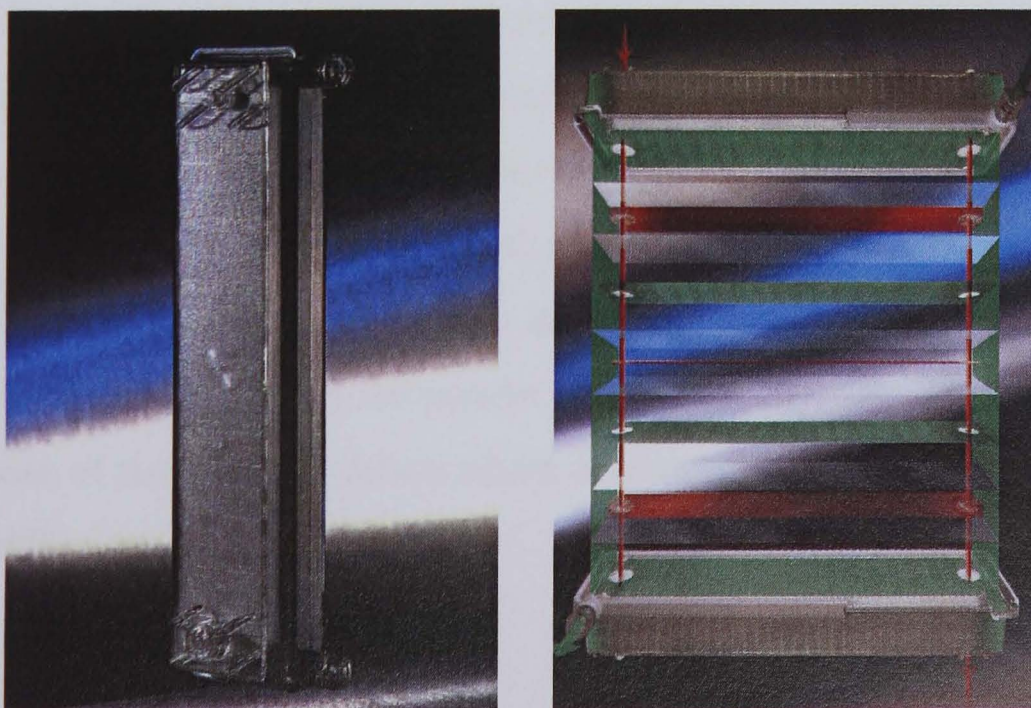
Figure 4-1. The Kidney (Source: Sainsbury's Magazine, 1995)

There, a large part of the liquid in the blood is squeezed out through small holes in the capillaries. The liquid contains water, waste products, salts and many nutritive substances. The primary urine is captured in 'Bowman's capsule' that surrounds the entire glomerulus. The primary urine is then concentrated. The greater part of the liquid, as well as salts and nutritive substances, are reabsorbed by the blood. What remains is urine, which is discharged to the bladder via the renal pelvis and the ureter (Jungmark, 1997).

4.3.1.2 Dialysis using a dialyser

In this form of treatment, the blood is conducted, via bloodlines outside the body, through the dialyser, where the purification takes place. In the dialyser, the blood and the dialysis fluid flow on opposite surfaces of a thin membrane. Waste products are transported from

Figure 4-2. The dialyser (Source: The Dialyser, Gambro's catalogue)



the blood through the membrane and carried away by the dialysis fluid. The body's excess liquid is removed through the membrane by means of a pressure differential created by the dialysis machine. The entire process is monitored and controlled by the dialysis machine (Gambro AB, 1997).

4.3.1.3 What is renal care?

When kidney function in a human being is lower than five percent, life-sustaining treatment is required in order to purify the blood. The technology for this is called dialysis, which has been available for more than 30 years. One alternative is to provide the patient with a transplant of a donated kidney. The kidney function then becomes, on the whole, as effective as it was before the disease set in. But transplants are not a viable solution for all patients. Availability of donated kidneys is limited and the body's rejection mechanisms make it difficult for the patient to retain the transplanted organ. Access to dialysis is therefore a matter of survival for kidney patients (Gambro Group Annual Report, 1995).

The number of dialysis patients in the world is increasing at a rate of about 9 percent annually and it is expected that at the end of the 1990's there will be approximately one million patients on dialysis. Of this number, 29 percent each are predicted in the United States and Japan with the Pacific Asia region, 26 percent in Europe and 10 percent in Latin America (Gambro Group Annual Report, 1995).

Most patients change the forms of treatment - haemo dialysis, peritoneal dialysis and transplants - several times during their life times. The patients who are treated with peritoneal dialysis generally perform the treatment - which can take place at home or in a work place by themselves. Those who have chosen haemo dialysis visit a clinic three times a week for treatment. There has been an increase in the number of people having haemo dialysis treatment at home. Dialysis treatment is one of the most resource-demanding forms of care since it does not result in any recovery of health and has to be maintained during the lifetime of the patient. Dialysis treatment is therefore a therapeutic area in the focus of the political debate about available resources for health care (Gambro Group Annual Report, 1995).

4.3.1.4 The types of equipment used in the renal unit survey

Four types of equipment were used in the renal unit survey, namely, Gambro AK-10, Gambro AK 90, Cobe Centry 2 and Cobe Centry 3. Their descriptions are as follows;

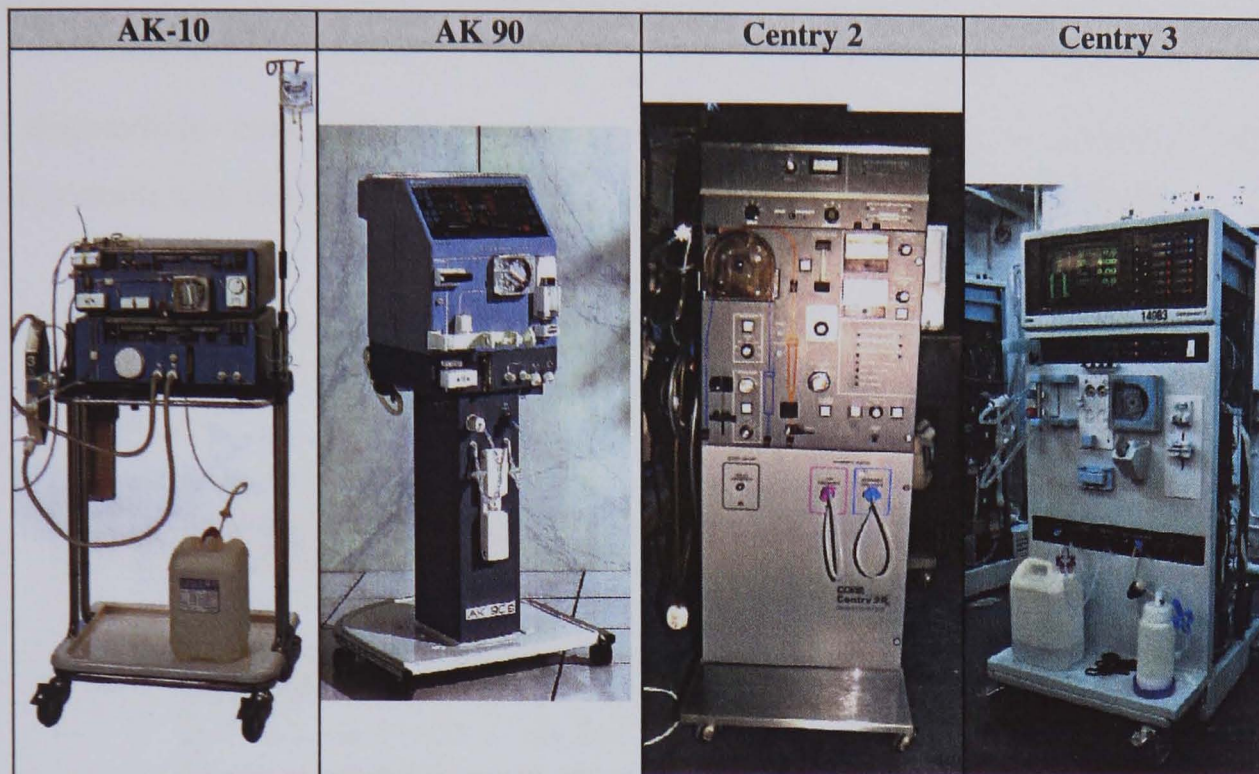


Figure 4-3. Four types of haemo dialysis

Gambro AK-10

The AK-10 system is designed around two basic building blocks, the blood monitor and the fluid monitor. The system can be expanded or modified by adding or interchanging monitors to meet a variety of needs and treatment techniques (Gambro AB, 1985).

Gambro AK 90

The Gambro AK 90 is a single patient haemo dialysis machine. The AK 90 consists of three units, namely, the blood unit, the fluid unit and the mixing unit.

The blood unit is designed to control and supervise the extra-corporeal blood circuit. Single needle treatment can be performed with one pump. To prevent coagulation, heparin may be administered by means of the integrated heparin-pump. The fluid unit is designed to administer the dialysis fluid and to control the ultrafiltration (AK 90 Operator's Manual, 1995).

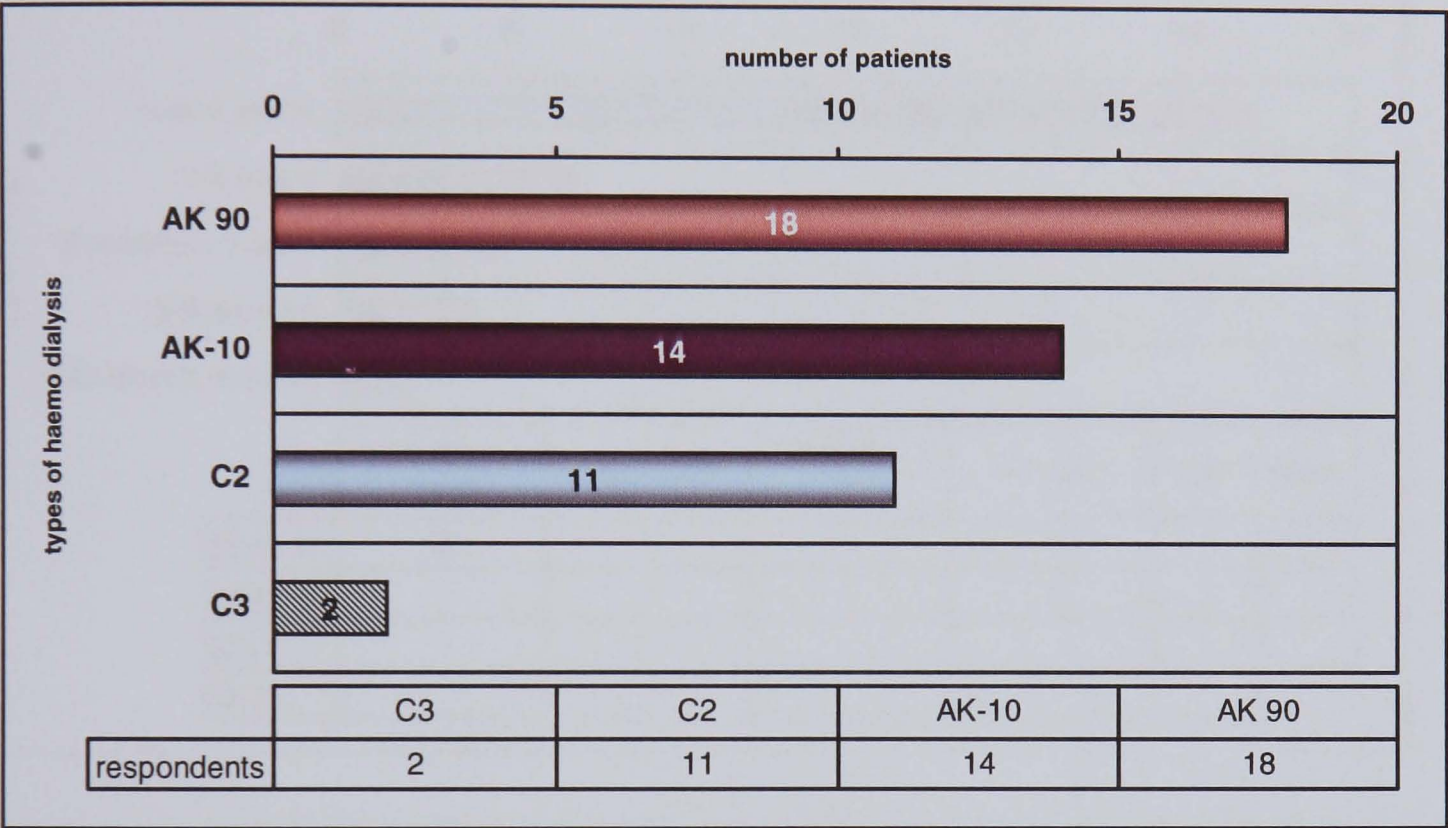
The details for Cobe Centry 2 (C2), Cobe Centry 3 (C3) and a detailed account of the control systems for haemo dialysis is provided in section 5.3.6 (see pp 176-182).

4.3.2 Results of the haemo dialysis user questionnaire surveys

Objective 1. To identify treatment & equipment types used.

Q1. What types of medical equipment / health care equipment are you using?

The total respondents were forty-five patients who used different types of haemo dialysis. The number of patients and the types of equipment used are illustrated in the table below; -



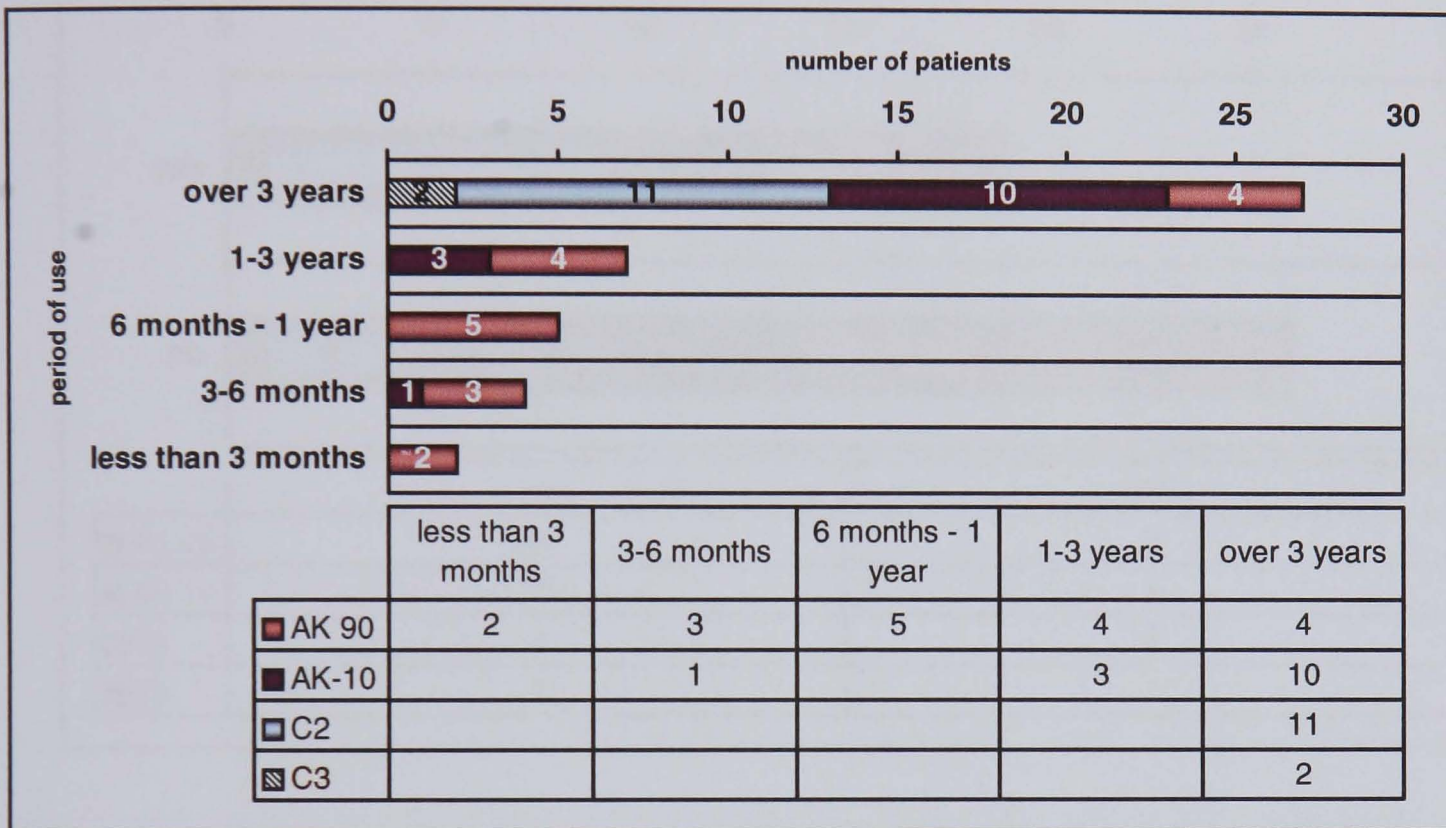
Hospitals	Types of haemo dialysis & patients
Oxford Churchill Hospital Renal Unit	AK 90: 13, C2: 11, C3: 2
Leicester General Hospital Renal Unit	AK-10: 14
Birmingham Queen Elizabeth Hospital Renal Unit	AK 90: 5

40% of respondents used Gambro AK 90, 31.1% of respondents used Gambro AK-10, 24.4 % of respondents used Cobe Centry 2 and only 4.4% of respondents used Cobe Centry 3.

Q2. How long have you been using this equipment?

The following options were available to tick an appropriate answer: -

- less than 3 months
- 3-6 months
- 6 months - 1 year
- 1-3 years
- over 3 years

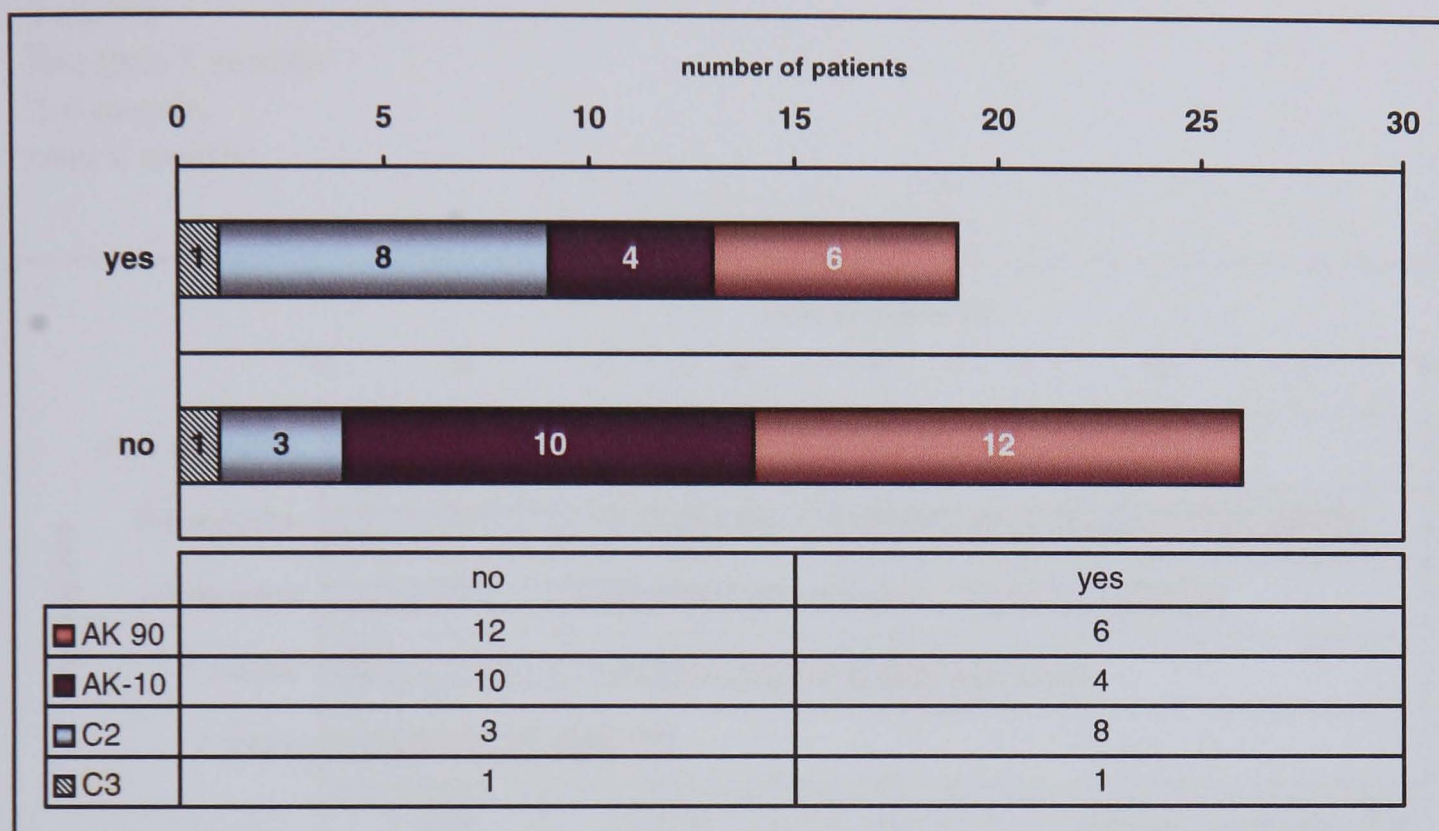


60% of respondents had used their equipment for over 3 years and 15.5% of respondents had used it for 1-3 years. Therefore, the majority of users were quite experienced patients.

Q11. Do you have any other hospital equipment and home use equipment, related to the same treatment?

Q12. If yes to 11. please give equipment names & what it is used for.

The options that were given to the respondents were to tick 'yes' or 'no' and then if 'yes' to Q11 they were asked to give the name of the equipment and its use.



Respondents	Product names & types
AK 90: 3, AK-10: 1, C2: 6	Blood Pressure Machine
AK 90: 1, C2: 2	Scale(weighing)
AK 90: 2, C2: 1, C3: 1	Elgastat Medico –Water purifier system (Reverse osmosis machine)
AK 90: 1	Portacabin – Storage
AK 90: 1, AK-10: 2	Gambro R/O unit
AK 90: 1	Ready Dialysis Machine (Portable)
C2: 1	Fresenius Ideamolyow 55
AK 90: 1	Unanswered

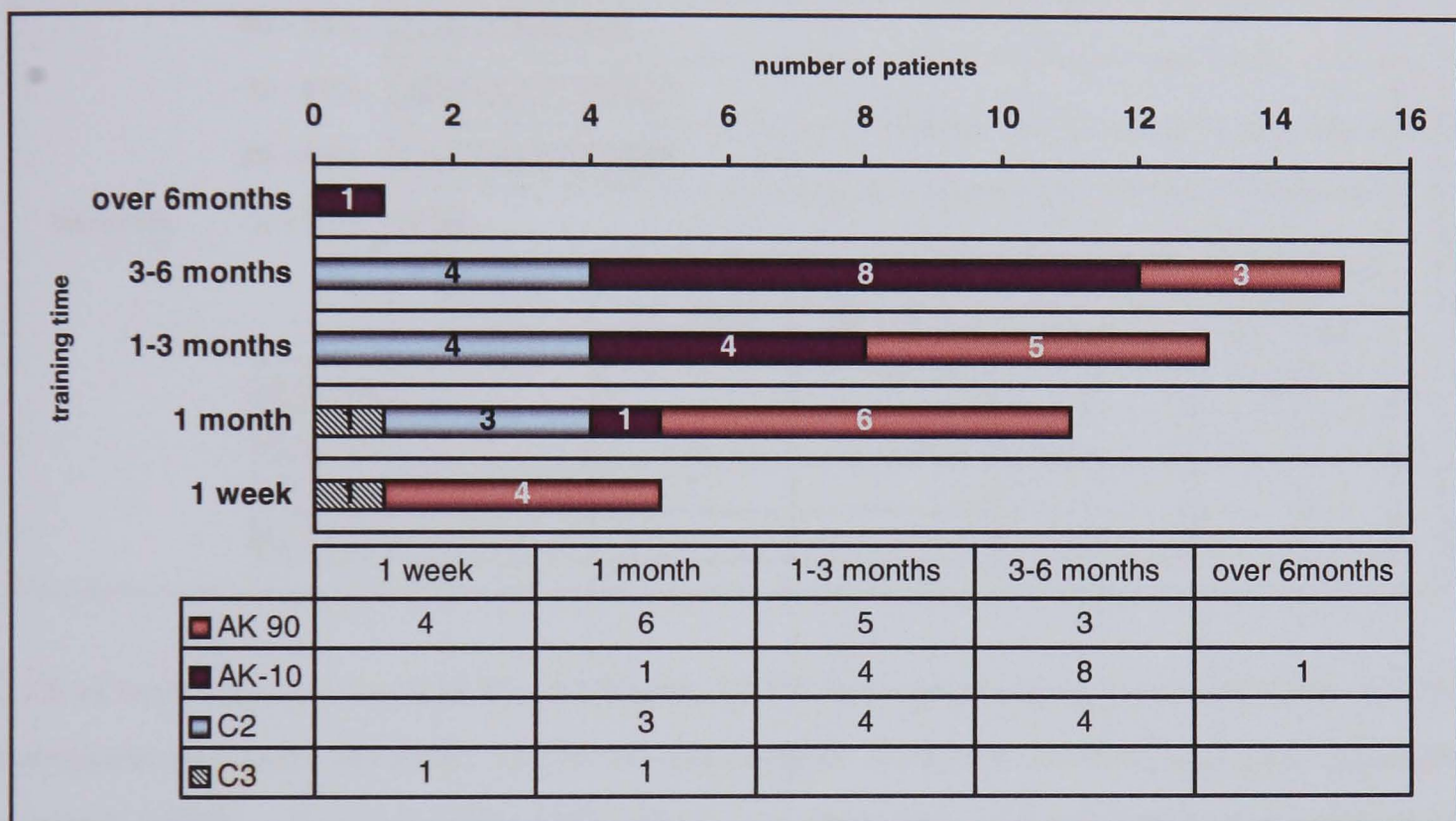
Except for the blood pressure machine and a weighing scale, most products stated above were provided with haemo dialysis. 19 patients (42.2%) answered 'yes' and 26 patients (57.8%) answered 'no'.

Objective 2. To identify the nature of equipment user training.

Q3. How long have you received training before using this equipment?

The following options were available for ticking: -

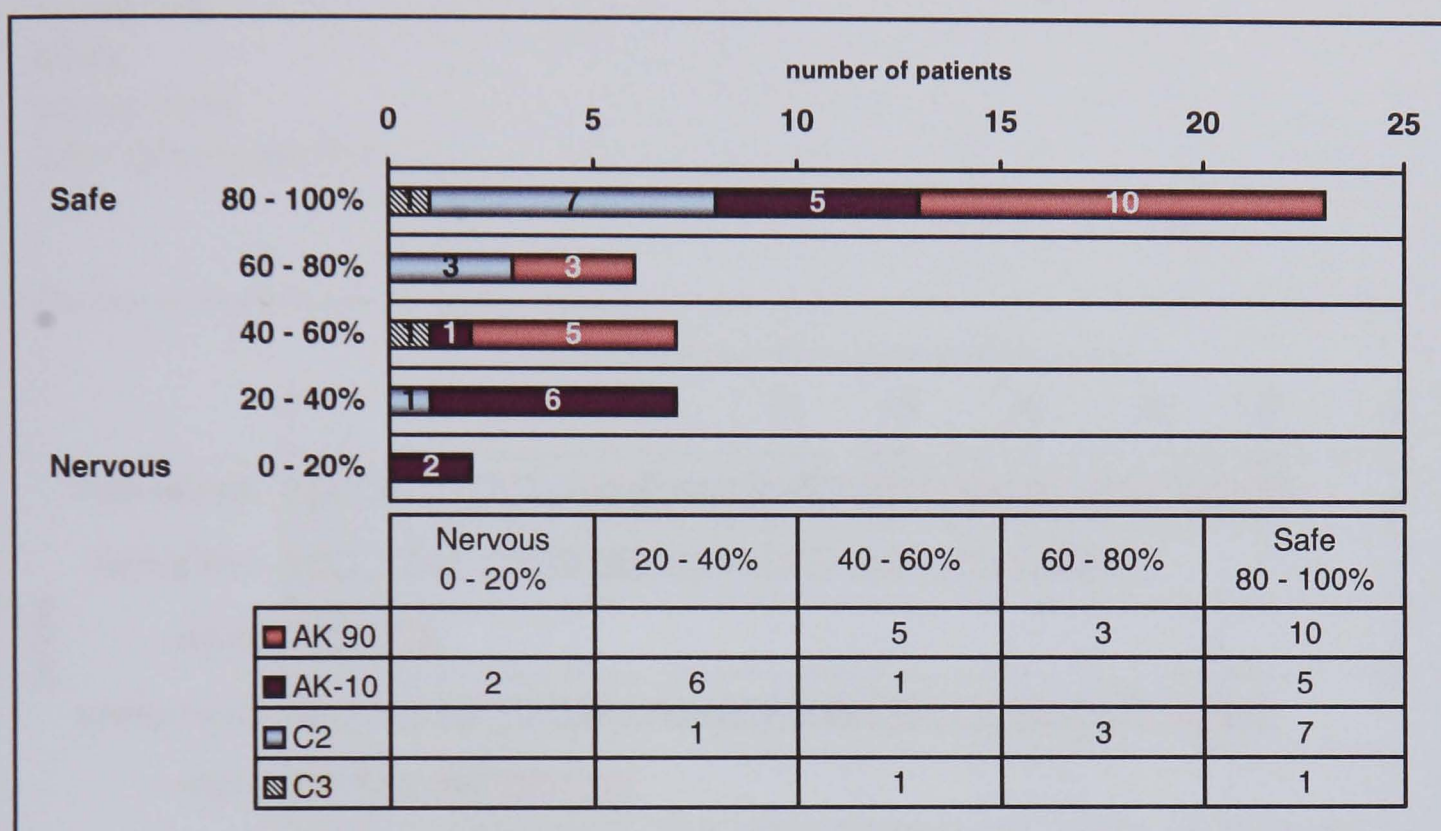
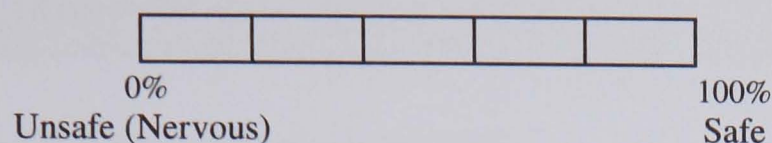
- 1 week
- 1 month
- less than 3 months
- 3-6 months
- over 6 months



One respondent had been trained for over 6 months, 33.3% of respondents had received training for 3-6 months, 28.9% of respondents had received training for 1-3 months, 24.4% of respondents had received training for 1 month and 11.1% of respondents had received training for 1 week. Therefore all users had received training before home use varying from at least 1 week to over 6 months. If the 'user friendliness' of the design of the haemo dialysis could be improved, the training period might be effectively reduced.

Q4. When you first used this equipment, how did you feel about it?

The following five point scale options were available for ticking: -



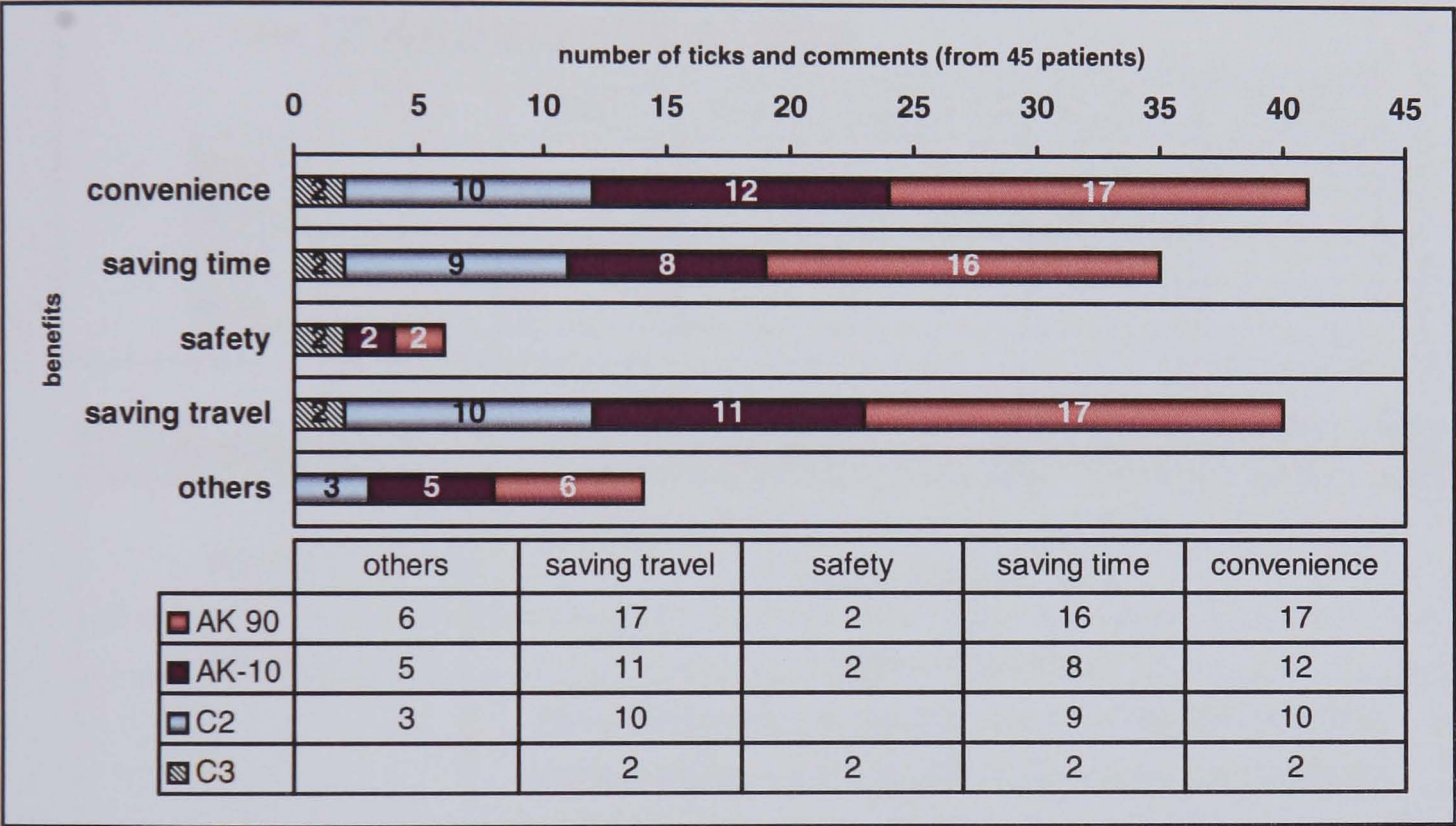
51.1% of respondents answered 80-100% safe, 13.3% of respondents answered 60-80%, 15.5% of respondents answered 40-60%, 15.5% of respondents answered 20-40% and two respondents answered 0-20%. Two possible explanations are that, one, a longer period of training and experience gave them a psychologically safer attitude and second, that they have forgotten how they felt when the equipment was first used. However, the 6 respondents with less than 6 months' experience of using the equipment gave answers that were not different from the other data.

Objective 3. To identify opinions about benefits of use.

Q10. What are the benefits of using this product at home?

The following options were available for ticking: -

- convenience
- saving time
- safety
- saving travel
- other (please specify) _____.

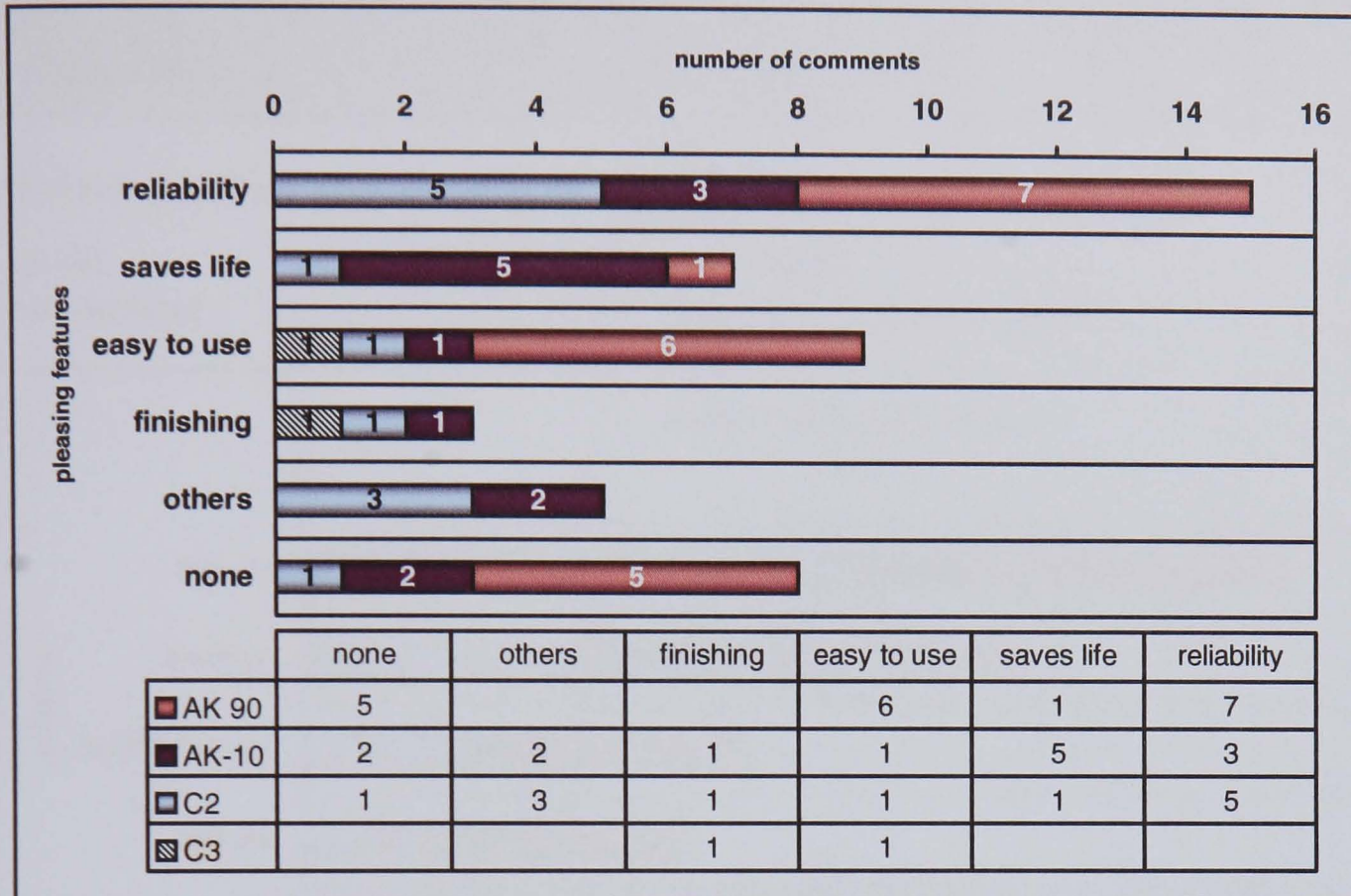


Respondents	Other benefits
AK 90: 4, AK-10: 1, C2: 1	Better life style
AK 90: 2, AK-10:3, C2: 1	Control of illness
AK-10: 1, C2: 1	At home, it is psychologically better. You are not associating with 'sick' people

45 respondents provided 136 ticks and other comments. 30.1% of ticks related to convenience, 29.4% of ticks related to saving travel, 25.7% of ticks to saving time, but only 4.4% of ticks related to safety as a benefit. Other comments (10.3%) were also given, as can be seen in the above table.

Q16. What is the most pleasing feature of your equipment?

No options were given.



Respondents	Other pleasing feature & comments
AK-10: 1	There are no pleasing features, it is a necessary evil. It must be used to keep me alive!
AK-10: 1	Dialysis is pleasing
C2: 1	When I first trained on the C2 it was user friendly in that it is painted on the front with blue & red lines & arrows to indicate positions of venous & arterial lines. Alarm lights etc. are easy to understand & if it alarms it is a matter of systematically looking for the problem.
C2: 1	Sensitivity
C2: 1	The Cobe C2 is not computerised. Any adjustments can be started out by the operator.

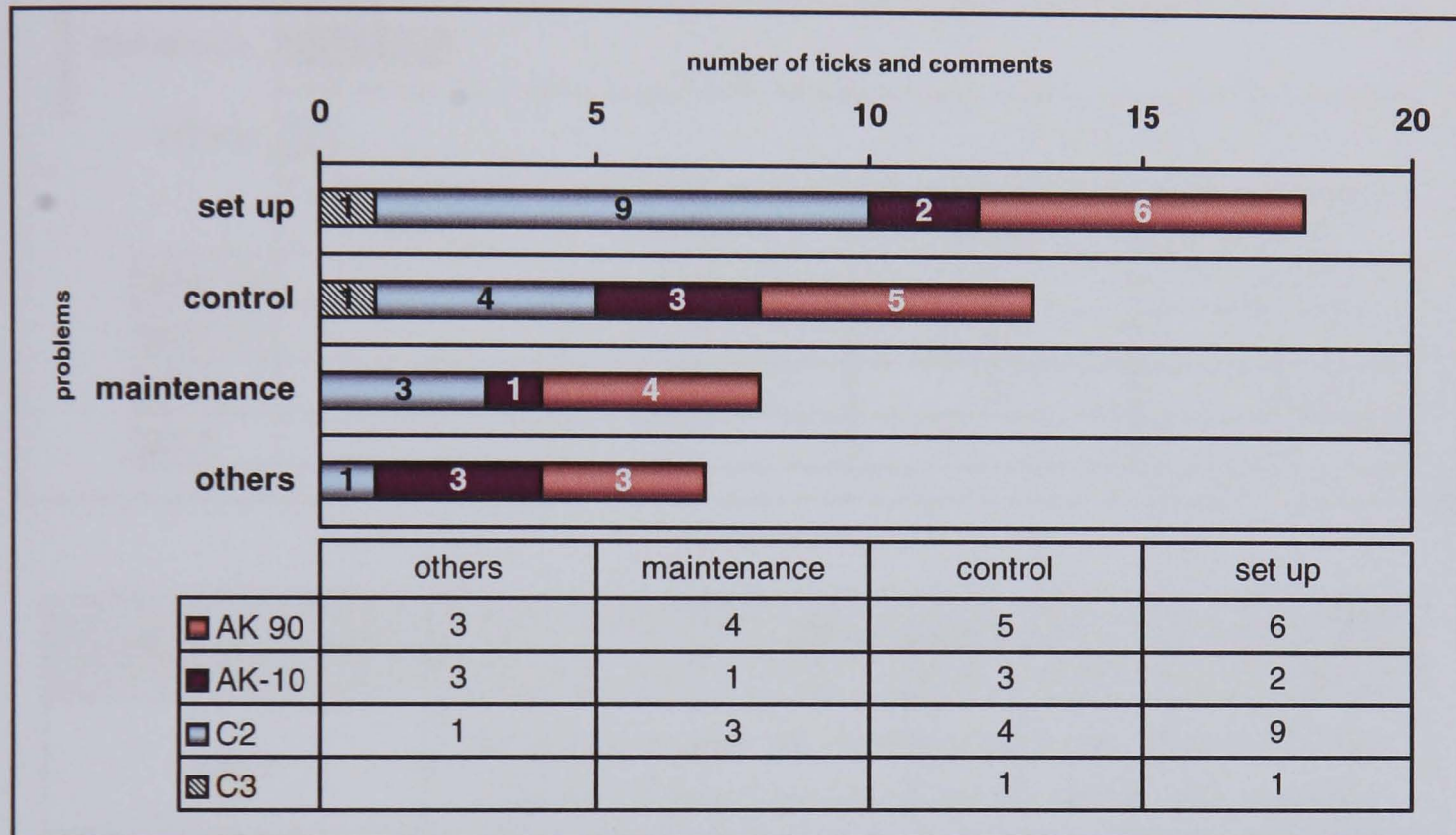
This was an open-ended question with varieties of answers. Content analysis was used to explore the answers. A total of 47 answers were provided; 31.9% of answers referred to reliability, 14.9% mentioned saving their life, for example, 'it keeps me alive', 19.1% related to ease of use, 6.4% referred to finishing and 10.6% of answers were other comments as above. As the above table shows one patient said dialysis is pleasing but another one said there are no pleasing features. This means that people have different psychological responses to using the same equipment (across the 4 equipment groups).

Objective 4. To identify opinions about problems of use.

Q5. When you first used this equipment at home, did you have problems with any of following?

The following options were available for ticking: -

- set up
- maintenance
- control
- other (please specify)

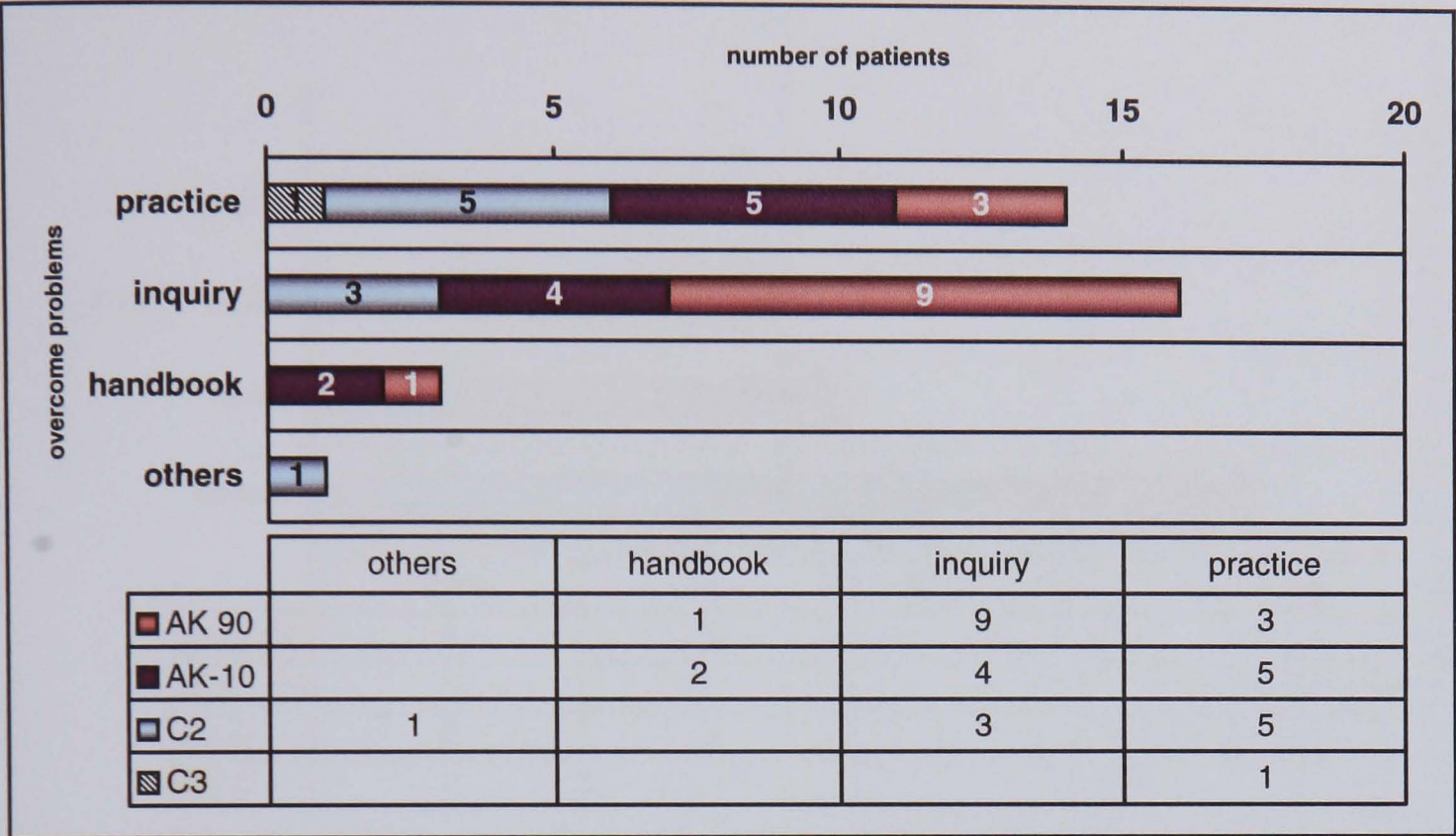


Respondents	Other comments
AK 90: 1	Filter/ sensor switch in acid line connector sticking
AK 90: 1	Bicarbonate powder kept closing up – liquid bicarbonate now used.
AK 90: 1	After the training period I was reasonably happy and now am very confident with the machine.
AK-10: 2	Breakdown/ emergency produce
AK-10: 1	Unanswered
C2: 1	The variety of problems was great, so it meant you had to have a great knowledge of the machine.

34 respondents provided 46 ticks and other comments, among them, 39.1% of ticks referred to problems with set up, 28.3% of ticks referred to problems with control, 17.4% of ticks to problems with maintenance; 15.2% referred to other problems, as seen in the above table. 11 respondents (AK 90: 5, AK-10: 3, C2: 2 and C3: 1) answered that they had experienced no problems.

Q6. How did you overcome these problems?

No options were given.

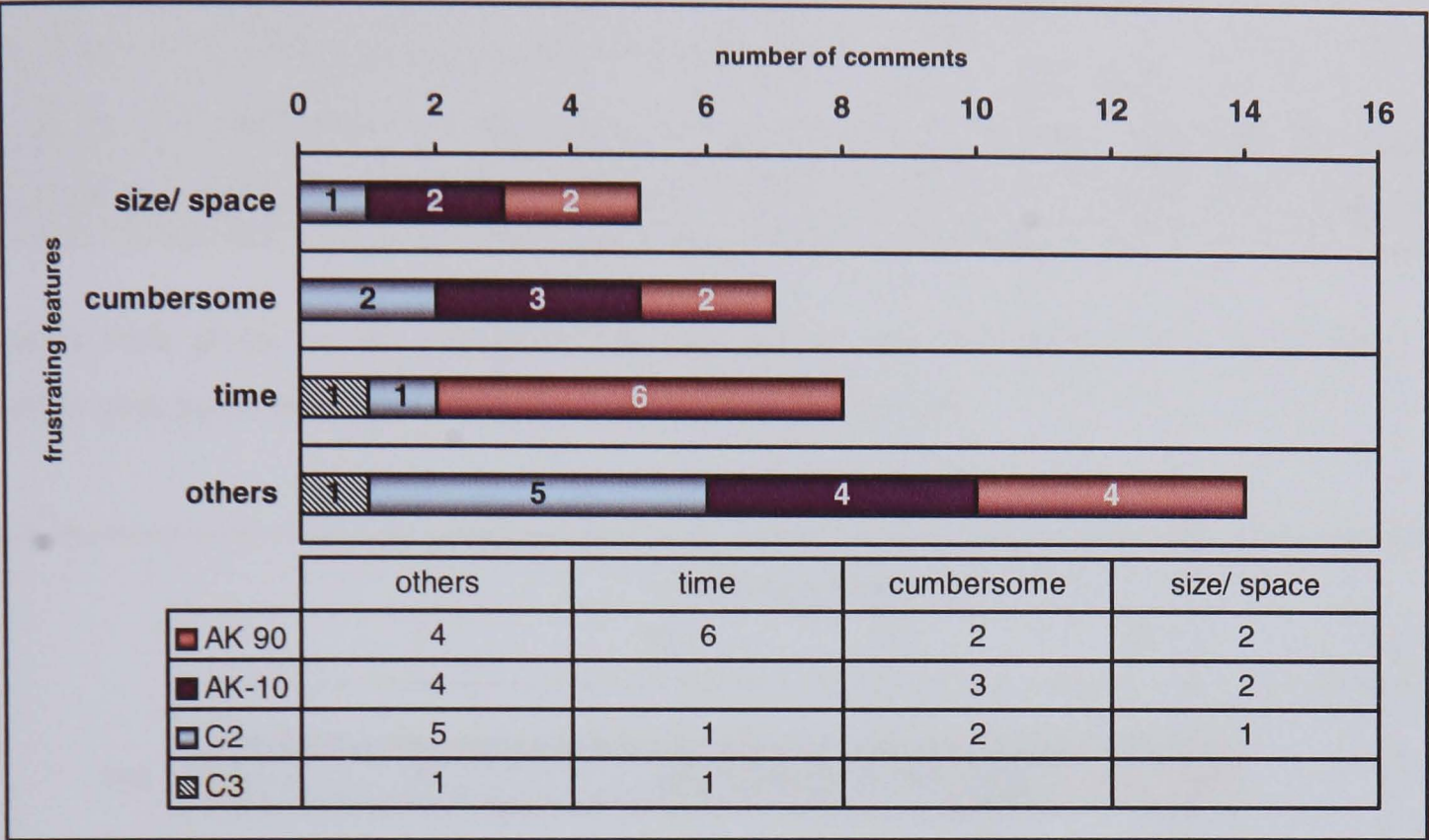


Respondents	Other comments
C2: 1	My confidence grew with perseverance. It was not a situation that could be avoided. If you did not use the machine you would die.

Content analysis was used to explore the answers. 34 respondents answered in addition to Q5, 41.2% of respondents answered practice, continue to use and experience, 47% of respondents answered inquiry to technicians, nurses and manufactures and only 3 respondents answered handbooks or manuals. One respondent gave another answer as above. Patients stated that there were many types of manuals and handbooks but those were difficult to understand, especially in an emergency.

Q15. What is the most frustrating feature of your equipment?

No options were given.



Respondents	Other comments
AK 90: 3	Length of time on dialysis – 4 hours + getting ready & clearing up, also having to mix large quantities of bicarb & water before each dialysis is a pain. I believe the bicarb could come ready for use.
AK 90: 2, AK-10: 2, C2: 3	Difficult to rectify machine faults without the need for technicians to be called out
AK 90: 1	Difficulty in excluding air from the blood lines.
AK 90: 1	Not being able to use a bicarb.
AK-10: 1	Contamination
AK-10: 1, C2: 2	The machine is installed in a very small bedroom and is very noisy. For over 4 hours I have to wear earplugs.
C3: 1	No display

This was an open-ended question and content analysis was used to explore the answers. 30 respondents provided 34 answers and other comments, among them, 14.7% of answers related to size and space, 20.6% to ‘cumbersome’, 23.5% to time spent using it and 41.2% were other comments as above. 15 respondents (AK 90: 7, AK-10: 6 and C2: 2) did not answer.

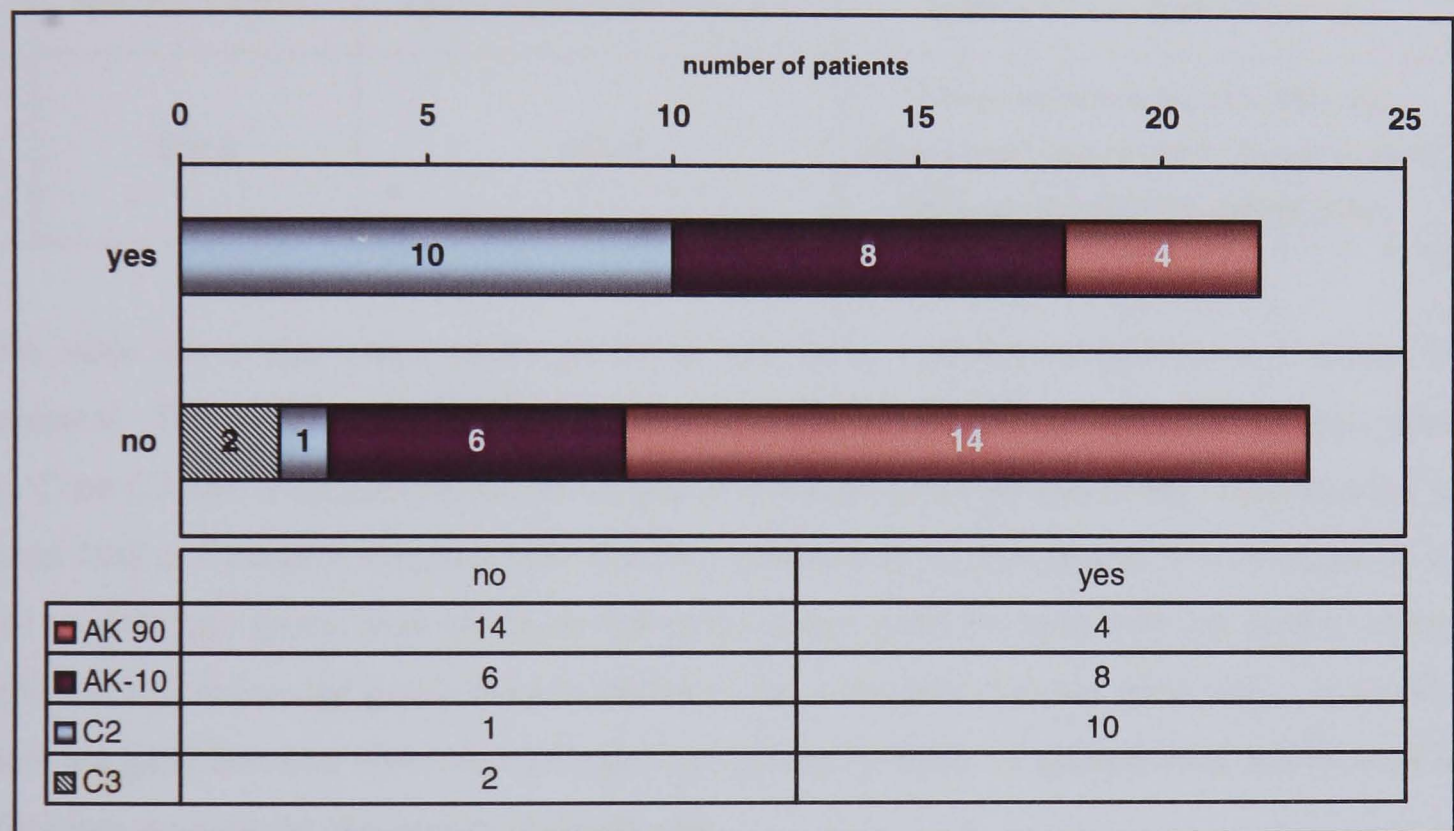
Objective 5. To identify opinions about availability/ loan/ ownership.

Q7. Do you know of any different (or better) equipment?

Q8. If yes to 7. Please give product names & types.

Q9. If yes to 7. What do you consider is better about this equipment in comparison with what you are currently using?

Options were given for the respondent to tick 'yes' or 'no' and then if 'yes' to Q7 they were asked to give name and types of equipment and then answer Q9.



49% of respondents answered 'yes' and 51% of respondents answered 'no'.

Many other types of haemo dialysis are available and information is also available. However, the respondents to this survey were restricted by lack of personal finance and access to information other than that obtained from nurses and other patients.

Patients stated that the haemo dialysis equipment was too expensive to buy. On the other hand, they thought that some way of financing could be found so that patients do not need to buy equipment themselves.

The following table gives product names & types and the reasons.

Current use	Different equipment	Comments
AK 90: 1	AK 95	Different not better
AK 90: 1	Cobe C3	Don't think it's better, just different
AK 90: 1	Cobe C2	Simpler to use, requires less time to set up and clean
AK 90: 2, AK-10: 1	AK 100	
AK-10: 1	BiCarb	Gives better treatment
AK-10: 5, C2: 5	More modern computerised	Quieter & up to date technology
C2: 5	AK 90	Patient friendly & smaller/ tells you clearly what has or has not been done & what needs doing on display panel.

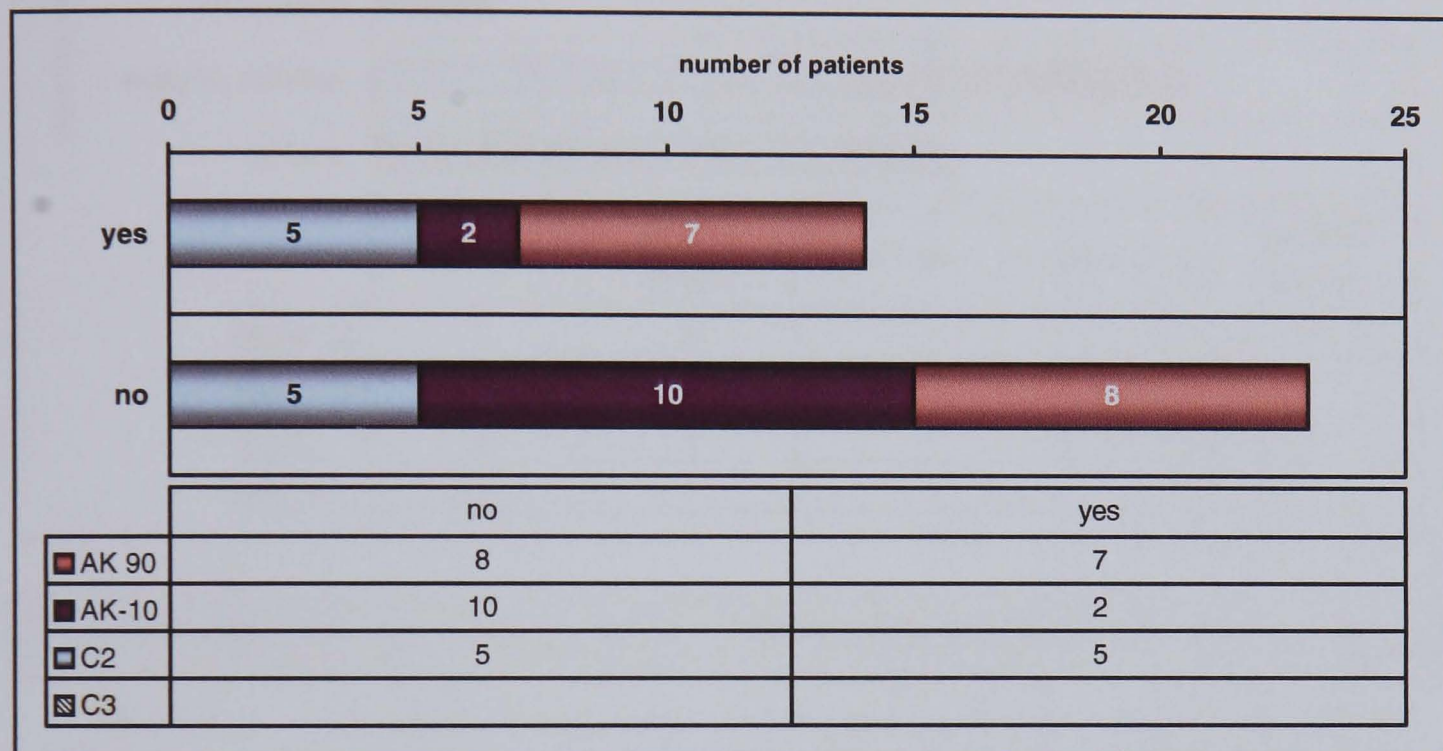
This table show that some users prefer to use more modern equipment and expect better treatment. However, one user of the AK 90 would have preferred to use an older style product, the Cobe C2 that is simpler to use and requires less time to set up and clean. A technician in the Renal Unit at Churchill Hospital said there are preferences by age group. For example he stated that an older age group want to use an old style control panel because they are used to using that style but a younger age group tend to prefer to use a modern computerised style. It shows that there are gaps between older and younger age groups in terms of preferences, which need to be taken into account for the design of equipment.

Objective 6. To identify opinions about any possible improvements.

Q13. Do you think there is a need for any other home-care treatments, if suitable equipment and help is provided?

Q14. If yes to 13. Can you suggest any examples?

Options were given for the respondents to tick 'yes' or 'no' and then if 'yes' to Q13 they were asked to suggest any examples.



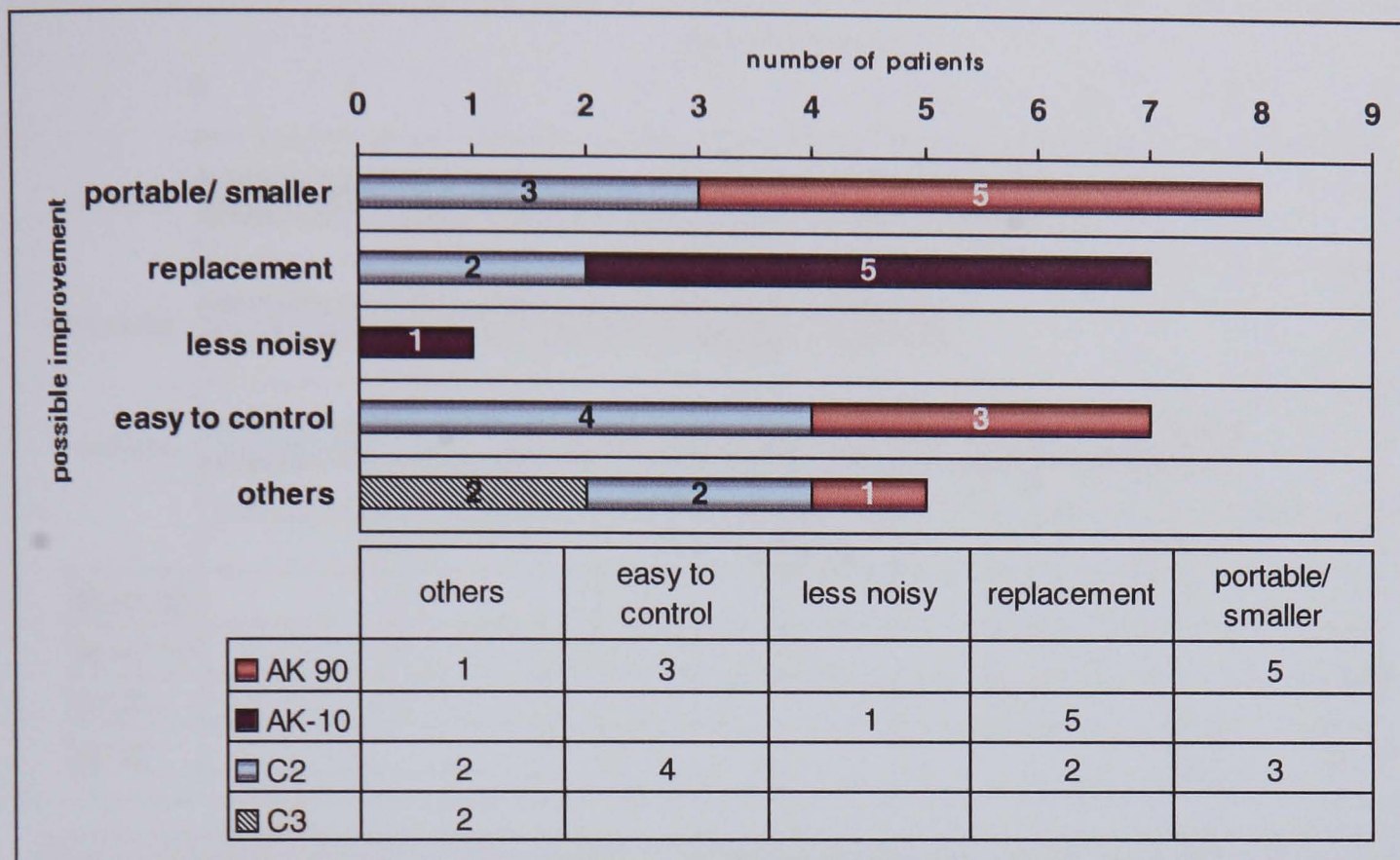
Respondents	Examples
AK 90: 3	If equipment could be made available for home use this would relieve the pressure on the hospital & help a near normal life.
AK 90: 1	Electric riser/ recliner chair
AK 90: 3, AK-10: 2, C2: 2	Blood sample equipment
C2: 1	AK 90
C2 : 1	A simple manual blood tester for potassium/ non-invasive measurement of blood glucose(using near-infrared(NIR) light technology) with alarms for too high/low states(see BDA balance issue no 158 Jul/Aug 97 p.68)
C2 : 1	Measure for taking blood samples & sending to be tested, to save on many visits to GP

37 respondents provided 37 ticks. 37.8% of ticks were 'yes', 62.1% of them were 'no'.

8 respondents (AK 90: 3, AK-10: 2, C2: 1 and C3: 2) did not answer. The above table suggests that there is an opportunity to design suitable equipment within patients' treatment areas and also other possible areas.

Q17. Could your equipment be improved & how?

No options were given

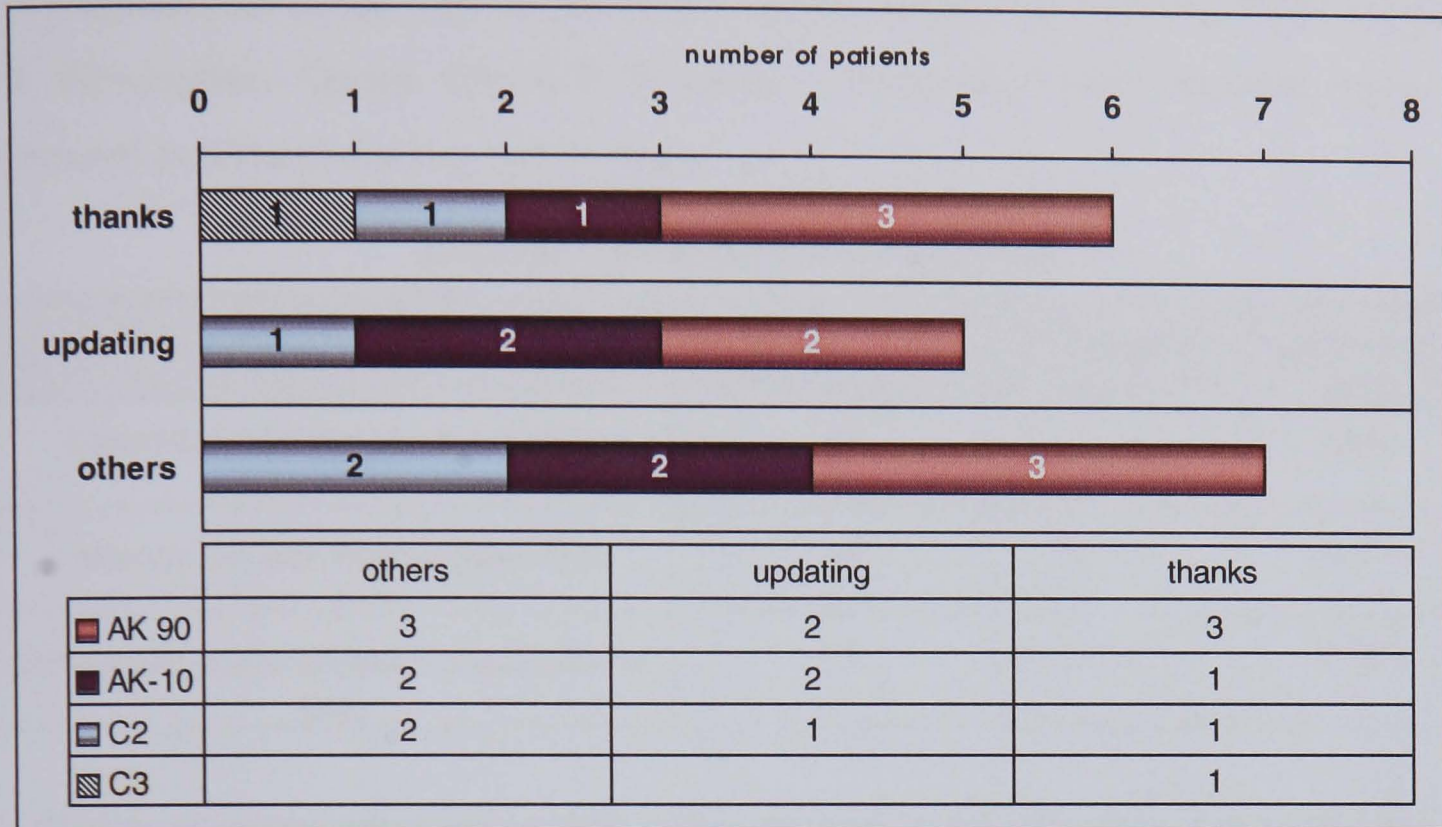


Respondents	Other suggestions
AK 90: 1	Provision of ready made solutions and a reduction in the cleaning cycle time.
AK-10: 5	Replacement with more modern equipment would give better and longer quality of life
C2: 2	Happy with it
C3: 1	Better software and consequently better display of information (like TV), infrared remote control to change settings, mute alarm etc.
C3: 1	It would be useful to have a signal at the end of a cleaning programme, as there is nothing at present. It would save power & the operator would not have to keep checking it.

This was an open-ended question and content analysis was used to explore the answers. 28 respondents provided suggestions. 28.6% of answers related to making more portable and smaller, 25% referred to replacement, 25% to easy to control, which shows that users have problems and difficulties with control. One suggestion was to make equipment less noisy. 17.9% were other comments as shown in the table. 17 respondents (AK 90: 9, AK-10: 8) did not answer.

Q18. Is there anything more you would like to say about the equipment you use?

No options were given.



Respondents	Other suggestions
AK 90: 1	All connections are too tight to be removed with one hand
AK 90: 1	Portable
AK 90: 1	Easier to understand
C2: 1	Less noisy
AK 90:2, C2: 1, C3:1	It keeps me alive/ a truly amazing machine, a credit to its designers and inventors.
C2: 2	Equipment has not been designed specially for home use.
C2: 1	When designing dialysis/medical equipment it is essential to bear in mind the patient's mind & thought processes are paralysed by fear. It could be easier to learn if the machine is in some way colour coded to indicate placement of tubes lines etc., or if certain processes, e.g. raising levels, etc., could be automatic. I have been offered a more modern machine to use at home but have refused as the controls are too high to reach from a reclining chair. Would be possible to design a remote control?

This was an open-ended question and content analysis was used to explore the answers. 18 respondents provided suggestions. Among the 18 respondents, 33.3% of answers related to express their thanks at having it, 27.8% referred to expect updating of their equipment, 38.9% of answers referred to the other answers as in the above table. 27 respondents (AK 90: 10, AK-10: 9, C2: 7 and C3: 1) did not answer. Opportunities clearly exist for improved design as suggested above.

4.4 Peritoneal dialysis user survey

This section provides another part of the analysis of a questionnaire survey carried out at 3 hospitals, the Renal Unit of Leicester General Hospital, Oxford Churchill Hospital and Birmingham Queen Elizabeth Hospital. Responses were received from 28 automated peritoneal dialysis (APD) users.

Table 4-3. Peritoneal dialysis respondents

Hospitals	Total APD patients	Patients responses	Response rate
Oxford Churchill Hospital Renal Unit	20	15	75%
Leicester General Hospital Renal Unit	13	11	84.6%
Birmingham Queen Elizabeth Hospital Renal Unit	6	2	33.3%

As discussed in the previous section, there are two most important forms of dialysis, which are haemo dialysis and peritoneal dialysis. This section discusses peritoneal dialysis, which is performed by introducing a dialysis solution into the peritoneal (abdominal) cavity through the catheter.

4.4.1 Description of equipment

4.4.1.1 What is peritoneal dialysis?

Peritoneal dialysis is an alternative form of dialysis, which differs from haemo dialysis in that the blood does not have to be brought outside the body.

This form of dialysis occurs inside the body. It uses the peritoneal membrane (the lining of the patient's abdomen) as the filter. For this treatment, a tube called a catheter is surgically placed through the wall of the patient's abdomen.

A special dialysis solution flows into the peritoneum through the catheter.

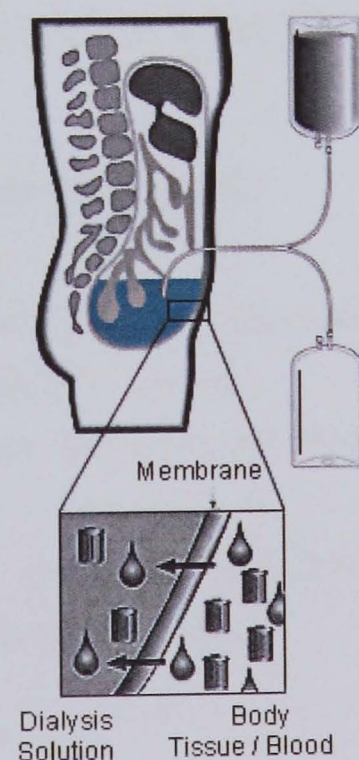


Figure 4-4. Peritoneal membrane

Waste products and excess fluids pass from the blood. They move through the peritoneal membrane, into the dialysis solution. Then, they are drained from the peritoneal cavity. Peritoneal dialysis can be performed by hand or by using a machine. Tubing and bags are worn only during the solution exchanges (Baxter International Inc., 1997).

4.4.1.2 Types of peritoneal dialysis

There are two types of peritoneal dialysis (PD). One is continuous ambulatory peritoneal dialysis (CAPD) and the other is automated peritoneal dialysis (APD).

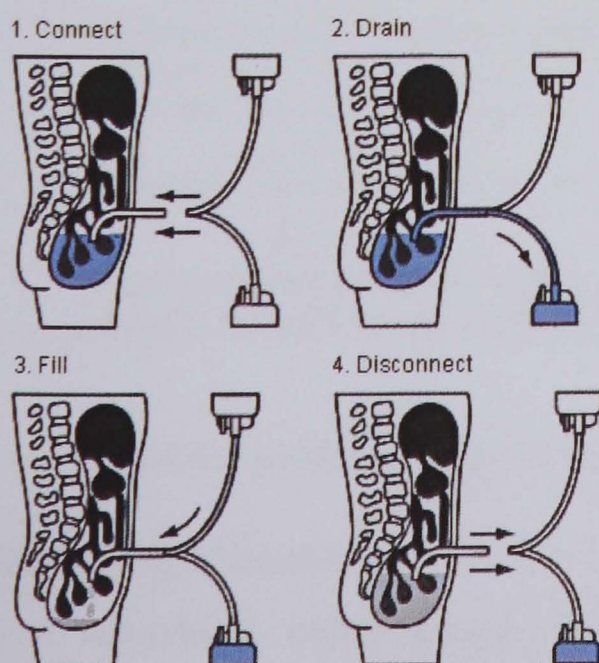
CAPD

Continuous ambulatory peritoneal dialysis (CAPD) allows gravity to draw dialysis solution into and out of the peritoneal cavity, using a system of tubing and bags. With CAPD, the patient connects tubing and a bag of sterile dialysis solution to the peritoneal catheter. By raising the bag to shoulder level or higher, the solution flows into the peritoneum. When empty, the tubing and solution bag can be removed and discarded.

During daily activities, the peritoneal membrane acts as a filter for a patient's blood. Waste products and excess water transfer to the dialysis solution. After a few hours, the patient attaches new tubing and an empty bag to the catheter. Then, the patient lowers the bag to drain the waste-filled fluid from the peritoneum.

The number of exchanges per day, and length of time per exchange, varies per person. Usually, CAPD is performed four times a day. Each solution exchange lasts about one-half hour (Baxter International Inc., 1997).

Figure 4-5. CAPD exchange (Baxter International Inc., 1997)



1. Connect the tubing set to the catheter.
2. Fill with the new solution.
3. Disconnect the tubing set from the catheter.
4. Throw away the used solution, disposable tubing and bags.

APD

APD uses a machine to perform the exchanges of dialysis fluid to and from the patient. The dialysis takes place during the night so that the patient needs to set up and programme the machine. Just before getting into bed, the patient attaches a line from the machine to the peritoneal dialysis tubing set and then switches it on. During sleep, the machine measures the amount of fluid, which goes in and comes out of the patient (Baxter, 1994).

APD is better for some patients because it frees them from performing dialysis exchanges during the day. It gives a therapy for those in regular employment, schoolchildren, and the elderly or infirm who need a carer to help them perform the dialysis. Another advantage of APD is that some patients achieve a better dialysis if the PD fluid is left inside them for a shorter time. This is much easier to accomplish during the night, using a machine, than during the day when the patient would have to perform extra dialysis exchanges. For extra therapy, dialysis solution remains in the peritoneal cavity during the day. The peritoneal cavity of most adults can hold about two to three quarts of fluid (Baxter International Inc, 1997).

There are several automated techniques that clinicians can use to manage ESRD patients. However, for medical reasons, some people are more suited to APD than others. The patients have a chance to discuss the different options offered by their dialysis centre with a doctor or nurse (Baxter, 1996).

Table 4-4. Peritoneal dialysis (Baxter International Inc, 1997).

Advantages of peritoneal dialysis	Disadvantages of peritoneal dialysis
Patient very involved in self-care Control over schedule/freedom Less restricted diet Typically, once a month clinic visit <i>No needles</i> More consistent physical condition Typically, no daytime exchange(APD)	Four exchanges per day Nightly machine exchanges(APD) Permanent external catheter Some risk of infections Potential weight gain Store supplies at home Body image change

4.4.1.3 Potential problems of peritoneal dialysis

As with many treatments peritoneal dialysis can have its problems. The main one being that of infection - either around the exit site (where the catheter comes out of the

abdomen) or inside the peritoneal cavity itself. Most infections are treated at home. During the initial training period, patients are trained how to minimise the risks of infection and recognise problems should they occur. Another problem to any form of dialysis may be fluid overload. When kidneys stop working, they are unable to control the amount of water lost in urine. This means that, invariably, renal patients pass little - if any - urine and are prone to retain excess water in body tissues. Again, patients are trained how to avoid water retention and what they should do in the event of a problem. All the main aspects of peritoneal dialysis are explained before discharge from hospital (Baxter, 1994).

4.4.1.4 The types of equipment used in renal unit survey

Four different types of equipment were used by patients taking part in the renal unit survey, namely, Baxter HomeChoice, Baxter PAC-XT, Gambro PD 100 and Fresenius PCS 2000. Their descriptions are as follows;

Baxter HomeChoice

The system enables people with kidney disease to self-administer the therapy overnight. HomeChoice uses air pressure rather than gravity to move fluids. The gravity simulation works by using two small chambers and an arrangement of valves combined in a disposable cassette. The cassette system is used, together with computer controlled pneumatic pressure to move the solution (Baxter Healthcare Corporation, 1994).

Figure 4-6. HomeChoice Automated PD System



Gambro PD 100

The cyclor controls and monitors the volume of dialysing fluid transferred to and from the patient by weighing the heater and drainage bags. All fluid flow is achieved using gravity and the waste fluid is collected in bags.

The PD 100 has a range of safety features, such as an automatic self-test, an over fill alarm and a 30 min battery back up (Gambro, 1990).

Treatment parameters are set using touch buttons and shown on digital displays. Alarm conditions are indicated by backlit panels (Gambro, 1994).

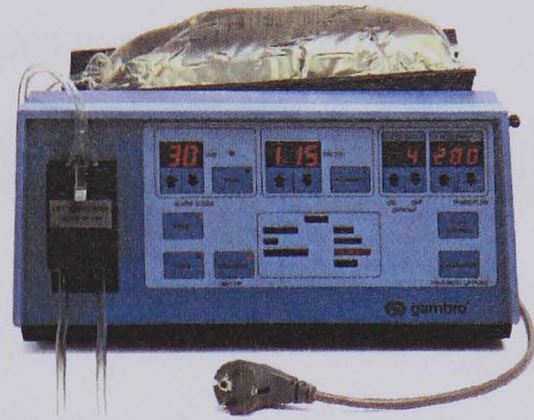


Figure 4-7. PD 100

Baxter PAC-XT

This machine is supplied in the UK by Baxter Healthcare Ltd. The inflow and outflow volumes, which are measured by weighing the heater and drain bags, are transferred to and from the patient under gravity. A pump is used to move fluid from the supply to the heater bag, and from the drainage bag to waste.

Treatment parameters are entered using function keys. Treatment date, messages and alarm conditions are displayed on two alphanumeric read-outs (Baxter, 1991).

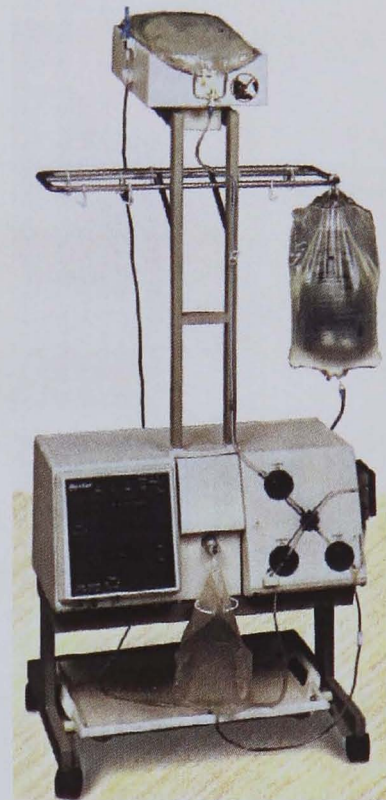


Figure 4-8. PAC-XT

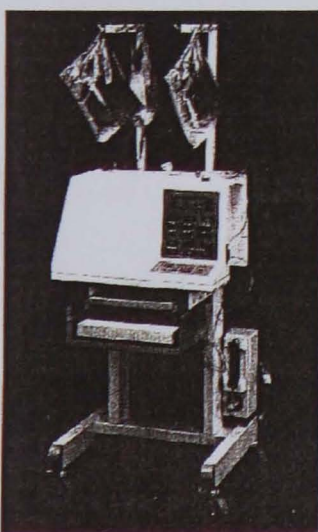


Figure 4-9. Fresenius PCS 2000

Fresenius PCS 2000

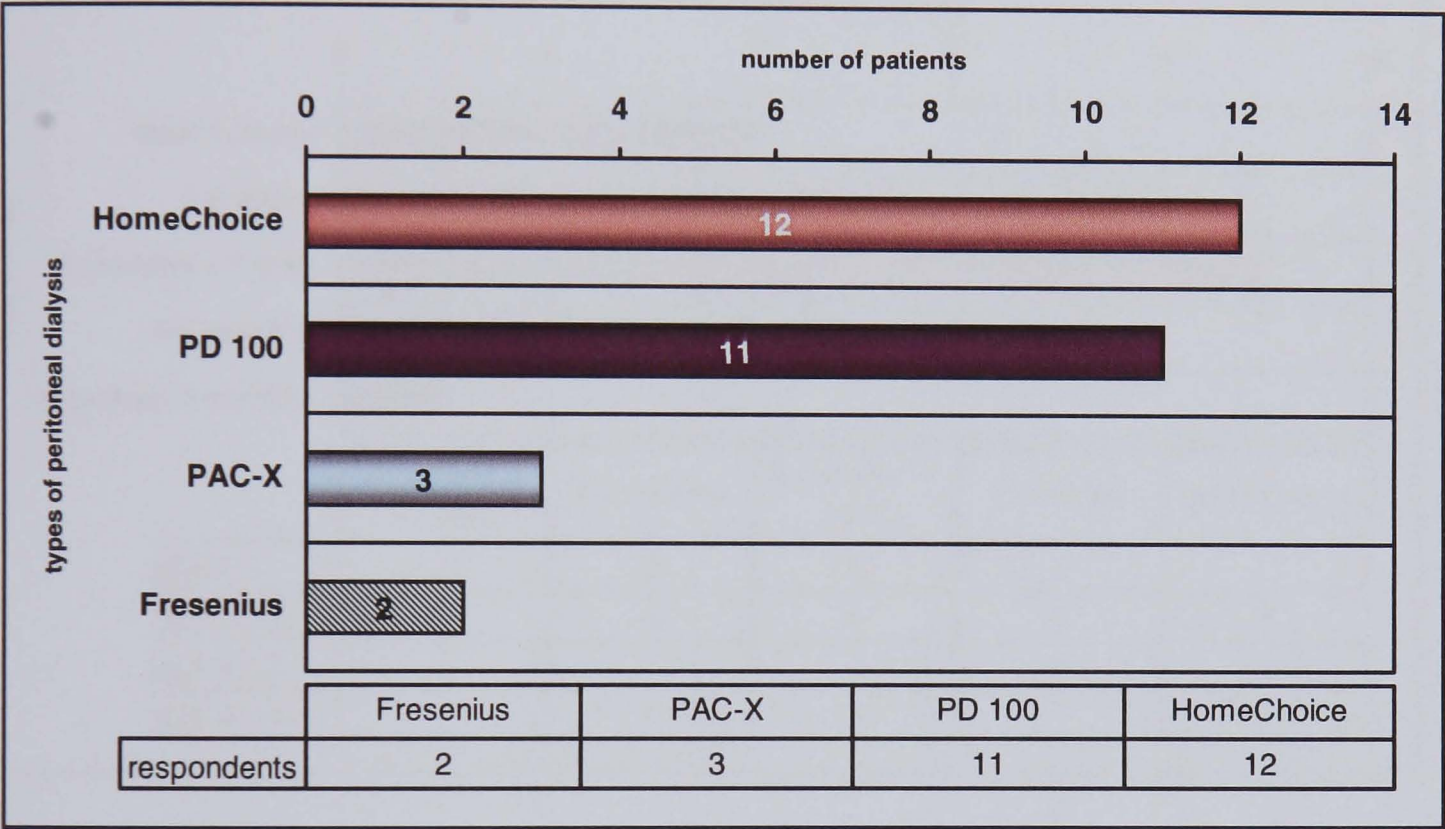
This product is manufactured in France by AAS, Fresenius. The cyclor transfers fluid to and from the patient under gravity or with pressure assistance. Inflow and outflow volumes are measured using burettes. Fresh fluid is pumped from the supply bag to the heater; waste fluid is collected in drainage bags (Fresenius, 1991).

4.4.2 Results of the peritoneal dialysis user questionnaire survey

Objective 1. To identify treatment & equipment types used.

Q1. What types of medical equipment / health-care equipment are you using?

The total respondents were twenty-eight patients using different types of peritoneal dialysis. The number of patients and the types of equipment used are illustrated in the table below; -



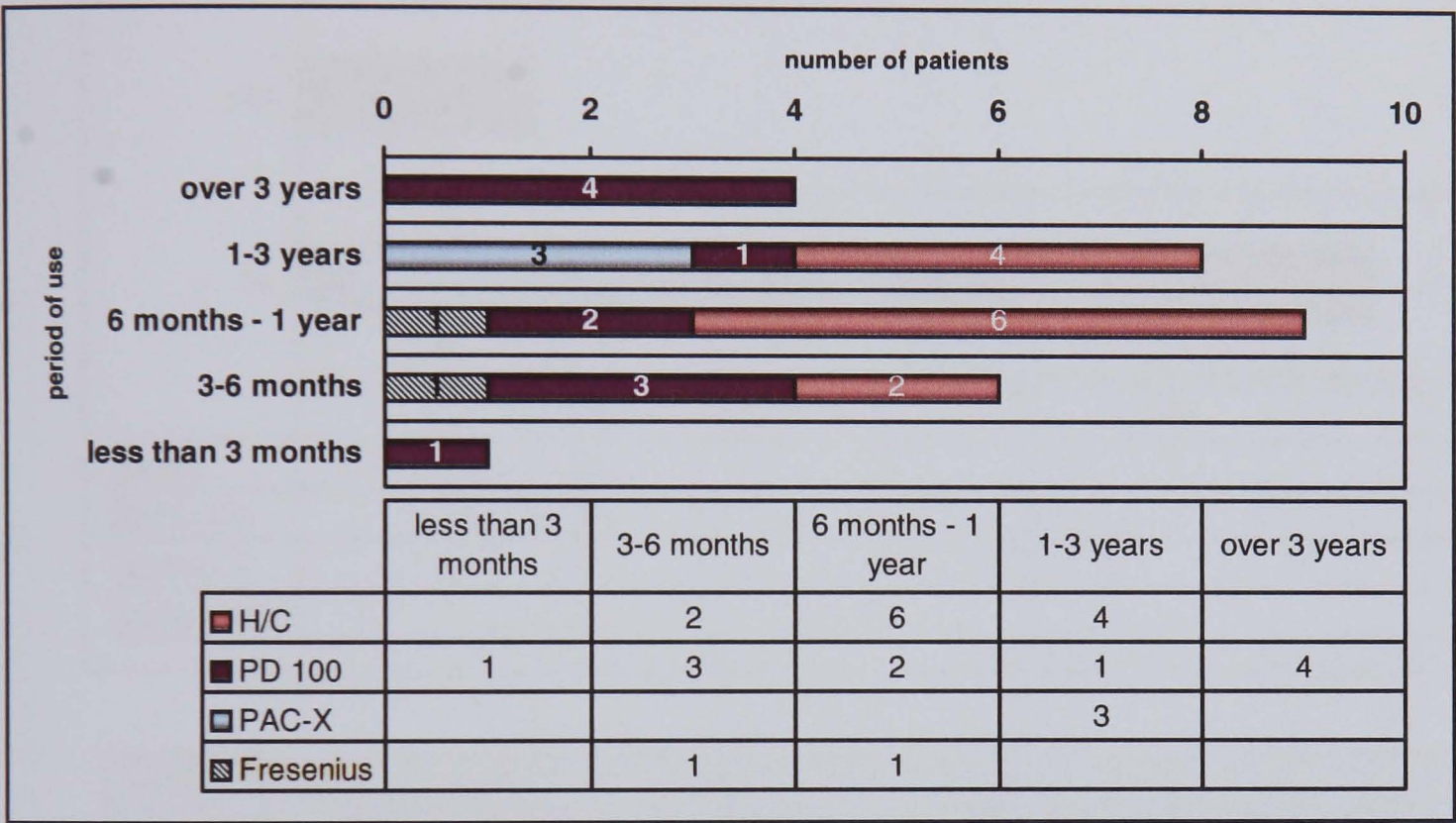
Hospitals	Types of peritoneal dialysis & patients
Oxford Churchill Hospital Renal Unit	H/C: 10, PAC-X: 3, Fresenius: 2
Leicester General Hospital Renal Unit	PD 100:11
Birmingham Queen Elizabeth Hospital Renal Unit	H/C: 2

42.9% of respondents used Baxter Home-Choice, 39.3% of respondents used Gambro PD 100, 3 respondents used Baxter PAC-X and 2 respondents used Fresenius.

Q2. How long have you been using this equipment?

The following options were available to tick an appropriate answer: -

- less than 3 months
- 3-6 months
- 6 months - 1 year
- 1-3 years
- over 3 years

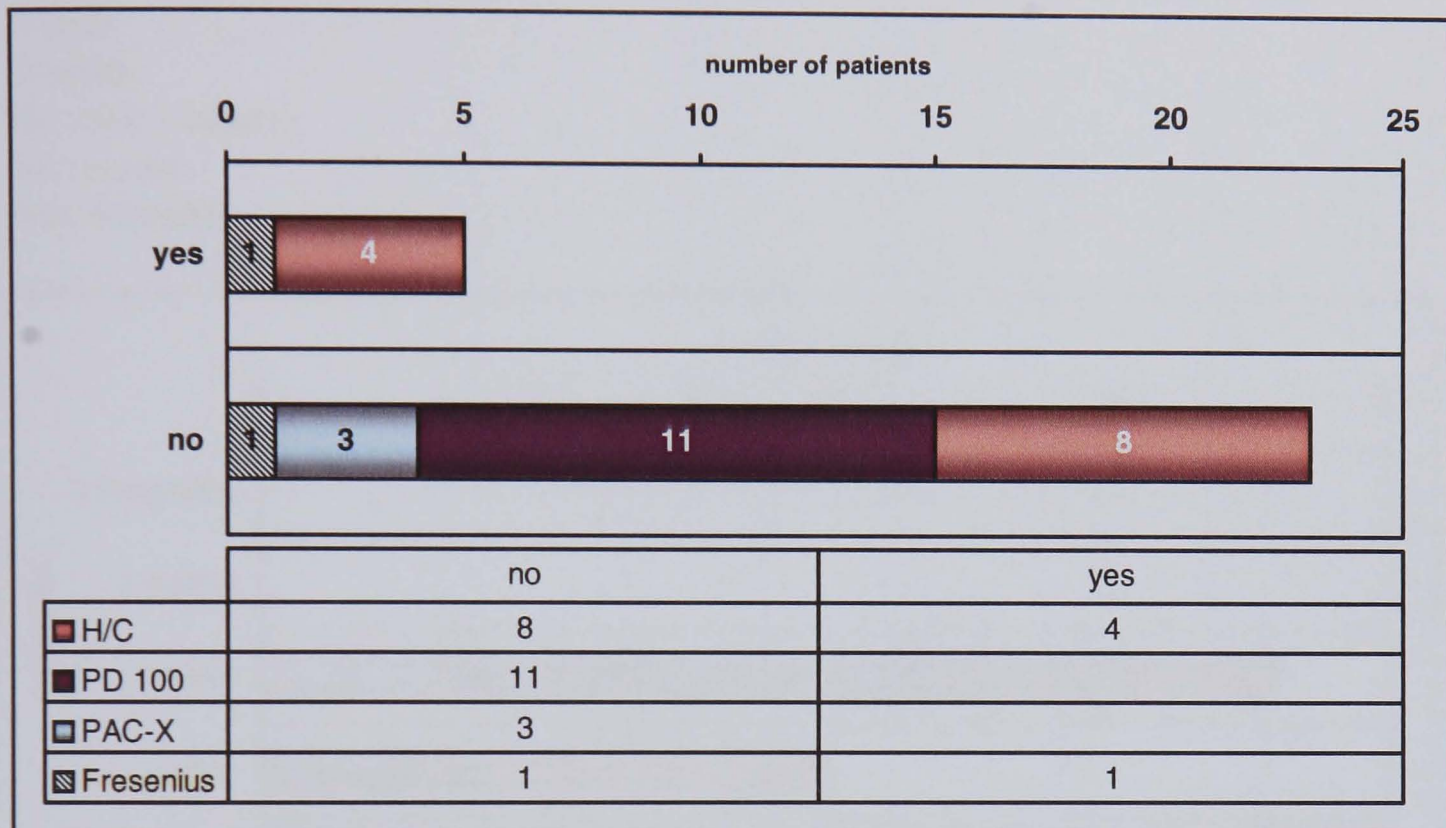


14.3% of respondents had used their equipment over 3 years, 28.6% of respondents for 1-3 years, 32.1% of respondents had used it for 6 months-1 year, 21.4% of respondents for 3-6 months and only 1 patient had been using the equipment for less than 3 months.

Q11. Do you have any other hospital equipment and home use equipment, related to the same treatment?

Q12. If yes to 11. Please give equipment names & what it is used for.

The options that were given to the respondents were to tick 'yes' or 'no' and then if 'yes' to Q11 they were asked to give the name of the equipment and its use.



Respondents	Product names & types
H/C: 3, Fresenius: 1	Blood Pressure Machine
H/C: 3, Fresenius: 1	Weigh scale
H/C: 2	Stethoscope
H/C: 1	Syringe Drive Type(MS 18)

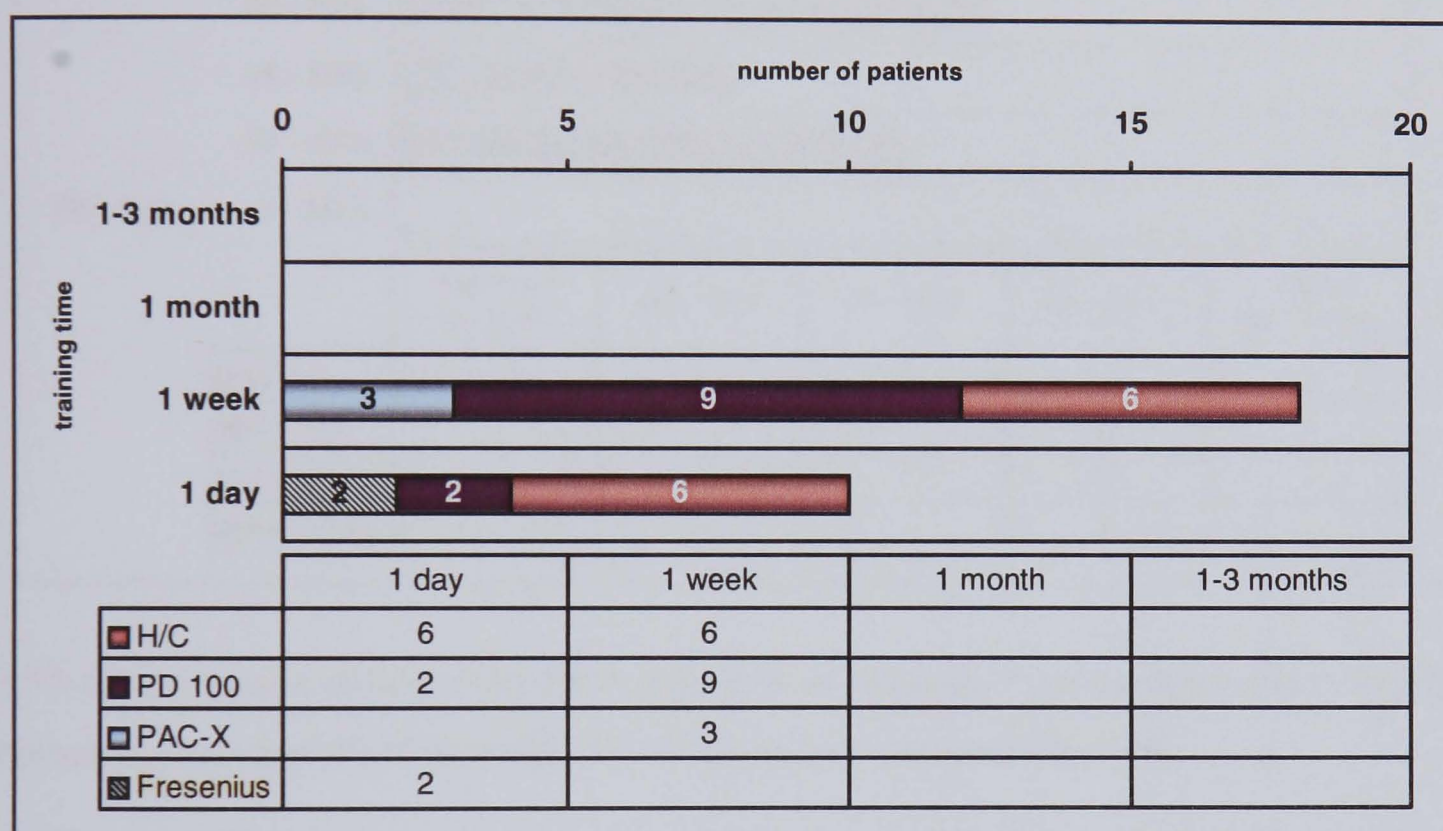
Only 5 patients (17.9%) had used other equipment and most patients (82.1%) had not.

Objective 2. To identify the nature of equipment user training.

Q3. How long have you received training before using this equipment?

The following options were available for ticking: -

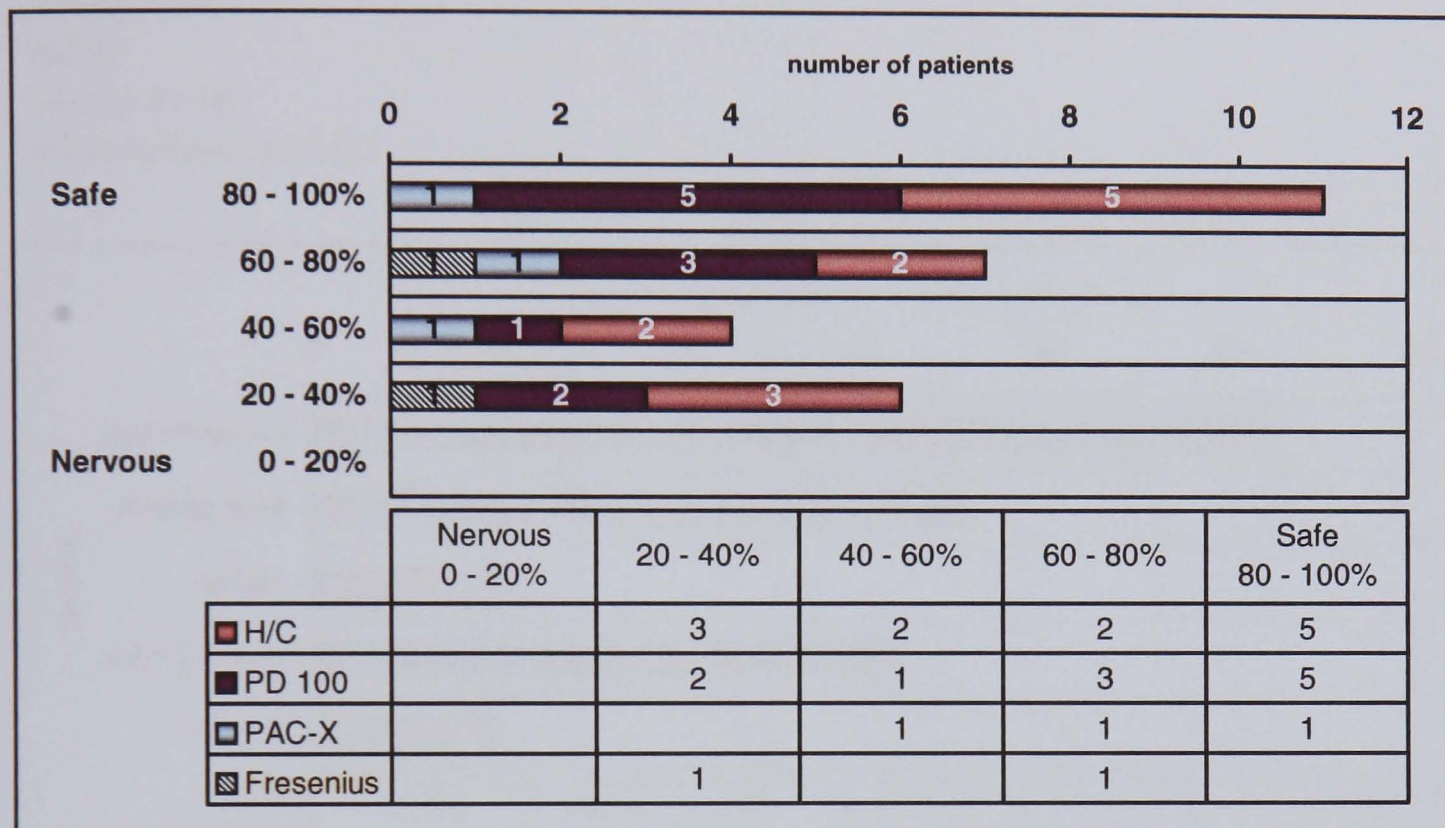
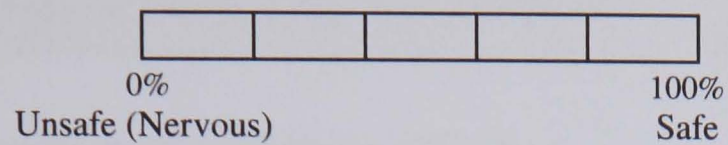
- 1 day
- 1 week
- 1 month
- less than 3 months
- 3-6 months
- over 6 months



64.3% of respondents had been trained for 1 week and 35.7% of respondents had received training for 1 day. All the users had received at least 1 day's training before home use. In comparison with haemo dialysis users this was a much shorter time period for training. This is because the system is much simpler to use as discussed in Section 5.3.5.

Q4. When you first used this equipment, how did you feel about it?

The following five point scale options were available for ticking: -



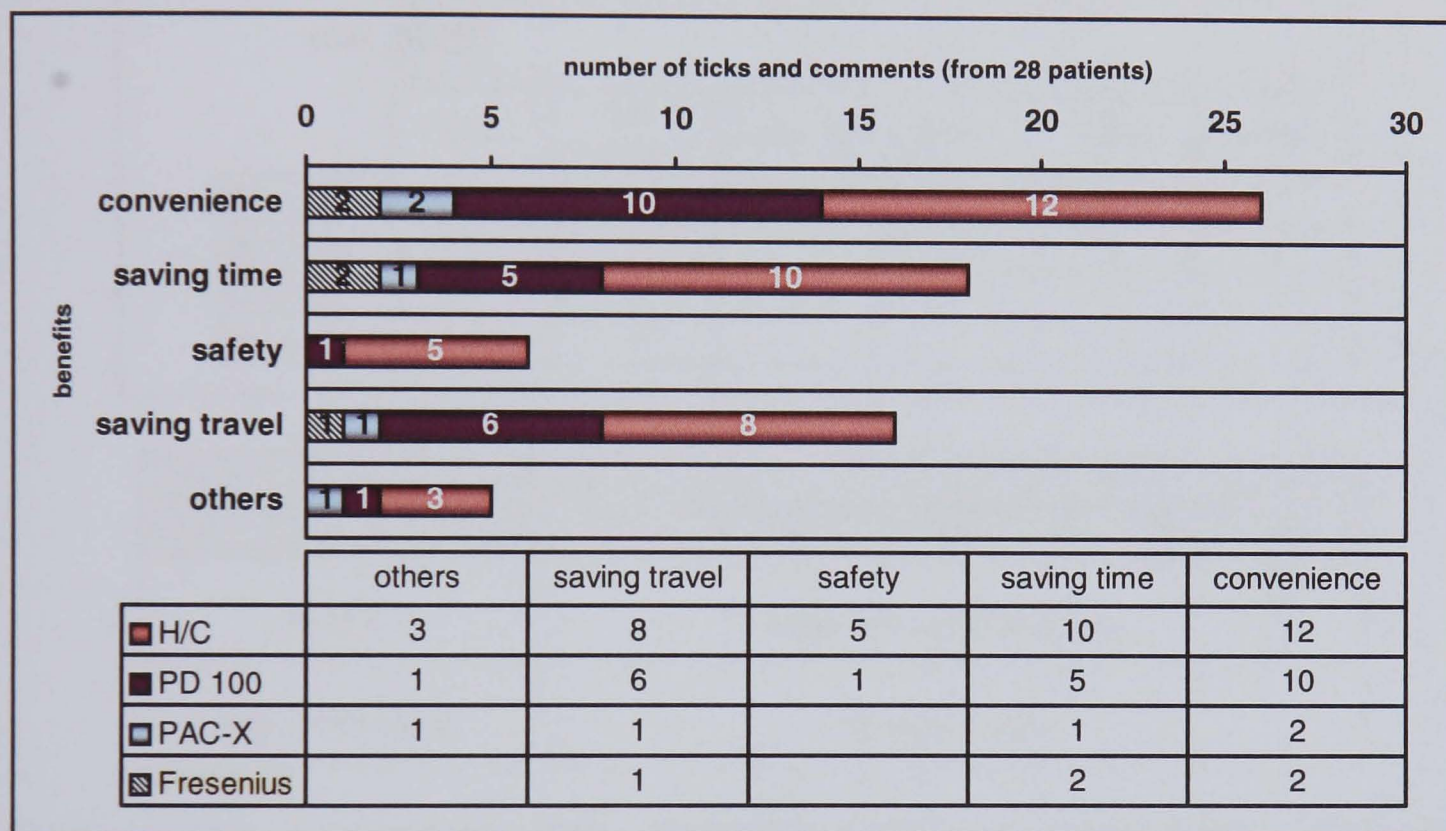
39.3% of respondents answered 80-100% safe, 25% of respondents answered 60-80%, 14.3% of respondents answered 40-60% and 21.4% of respondents answered 20-40%.

Objective 3. To identify opinions about benefits of use.

Q10. What are the benefits of using this product at home?

The following options were available for ticking: -

- convenience
- saving time
- safety
- saving travel
- other (please specify) _____.

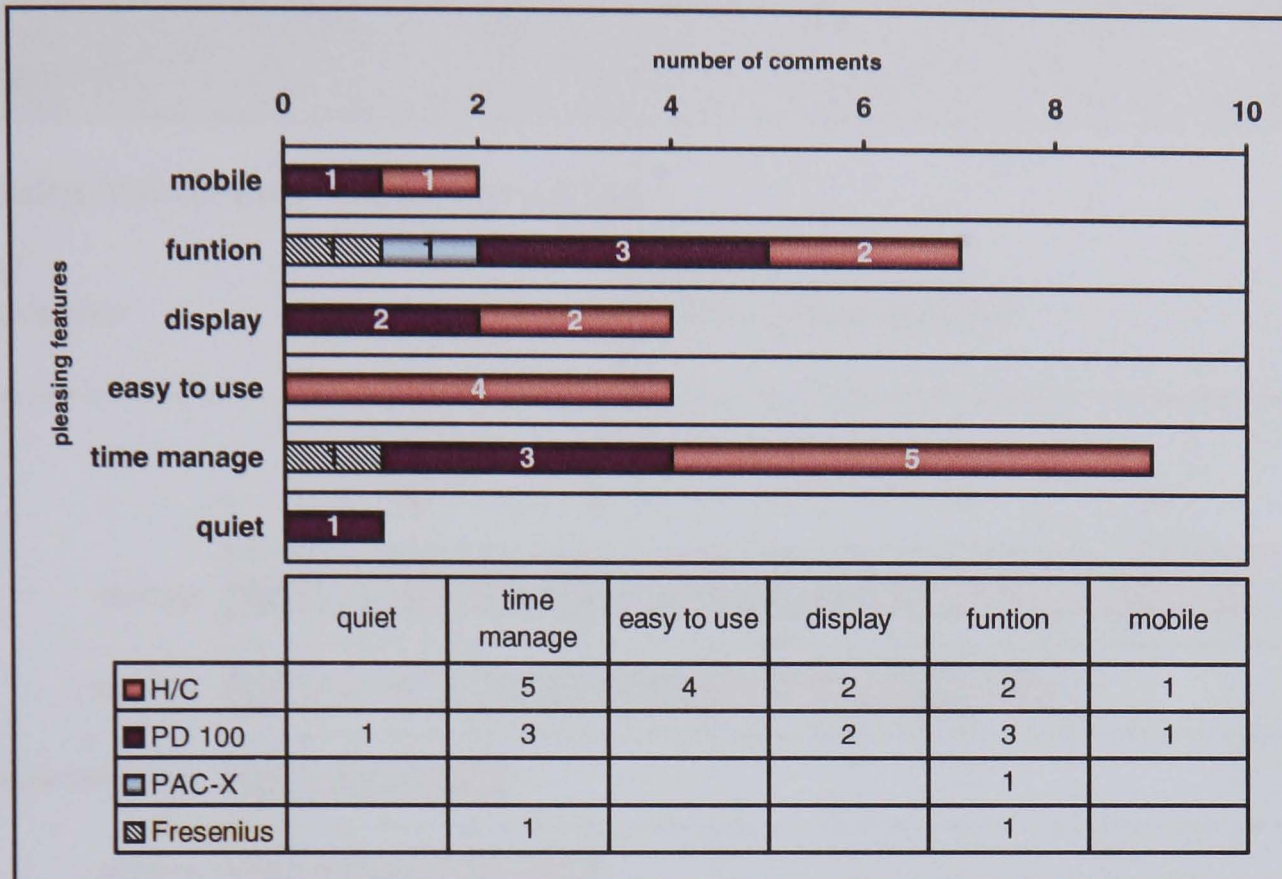


Respondents	Other benefits
H/C: 1	More independent life style-10h/week
H/C:1	Ability to lead a new normal daily life & being able to take it on holiday etc.
H/C: 1	Control over own treatment.
PD 100: 1	Felling better than I did with the other method of dialysis i.e. Haemo dialysis & CAPD.
PAC-X: 1	Can use overnight

28 respondents provided 71 ticks and other comments, 36.6% of ticks related to convenience, 22.5% of ticks related to saving travel, 25.3% of ticks to saving time, but only 8.5% of ticks related to safety as a benefit. Other comments (7%) were given, as can be seen in the above table.

Q16. What is the most pleasing feature of your equipment?

No options were given.



Respondents	Other pleasing feature & comments
H/C: 1	Days are completely free
H/C:1, PD 100:1	Keep me alive

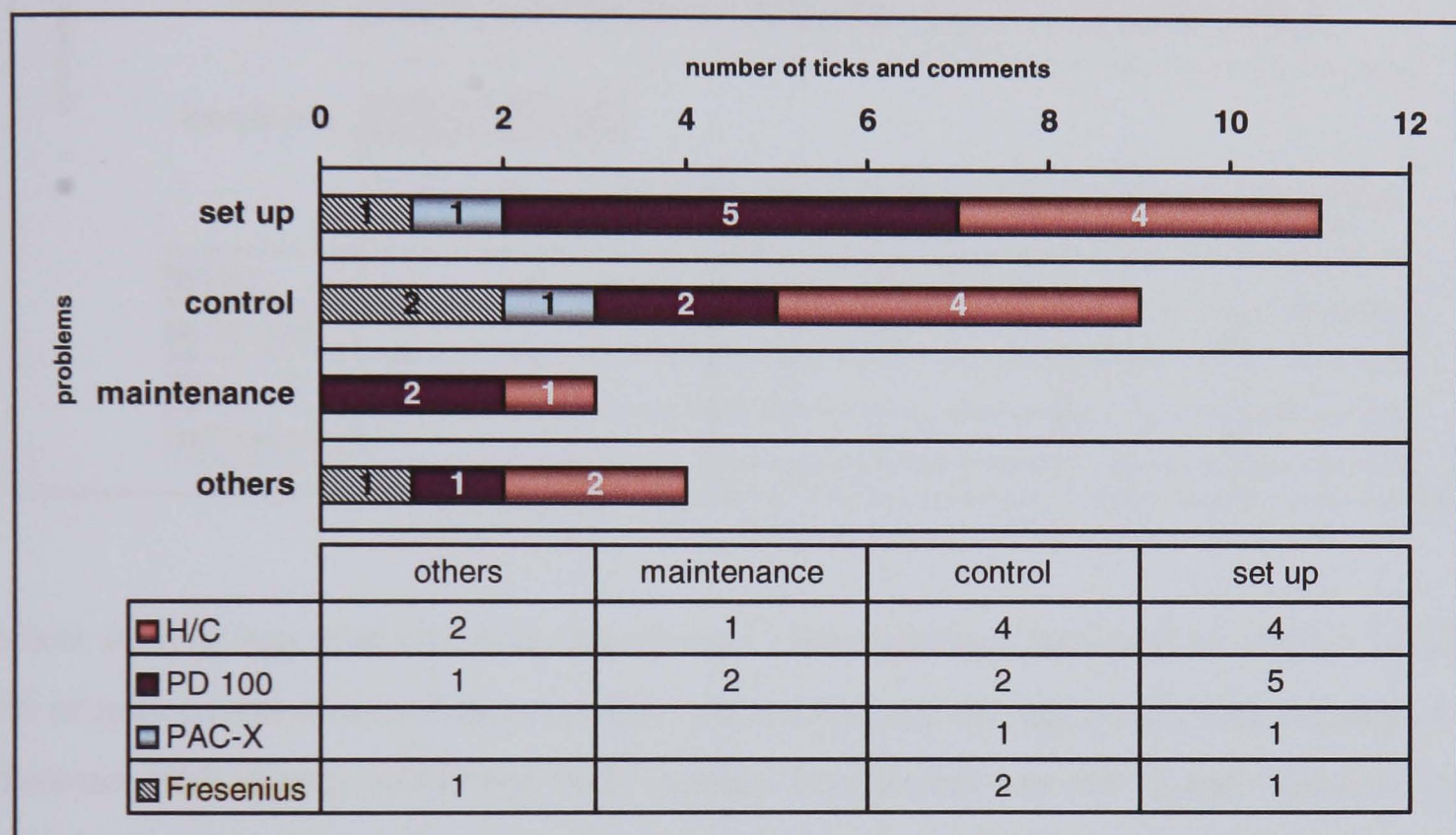
This was an open-ended question with varieties of answers and content analysis was used to explore the answers. 24 respondents provided 27 answers, among them, 33.3% related to time management, 25.9% of answers referred to function, 14.8% related to ease of use, 14.8% referred to display, two answers related to mobile, one answer referred to quiet. 4 respondents (H/C: 1, PD 100: 1 and PAC-X: 2) did not answer.

Objective 4. To identify opinions about problems of use.

Q5. When you first used this equipment at home, did you have problems with any of the following?

The following options were available for ticking: -

- set up
- maintenance
- control
- other (please specify)

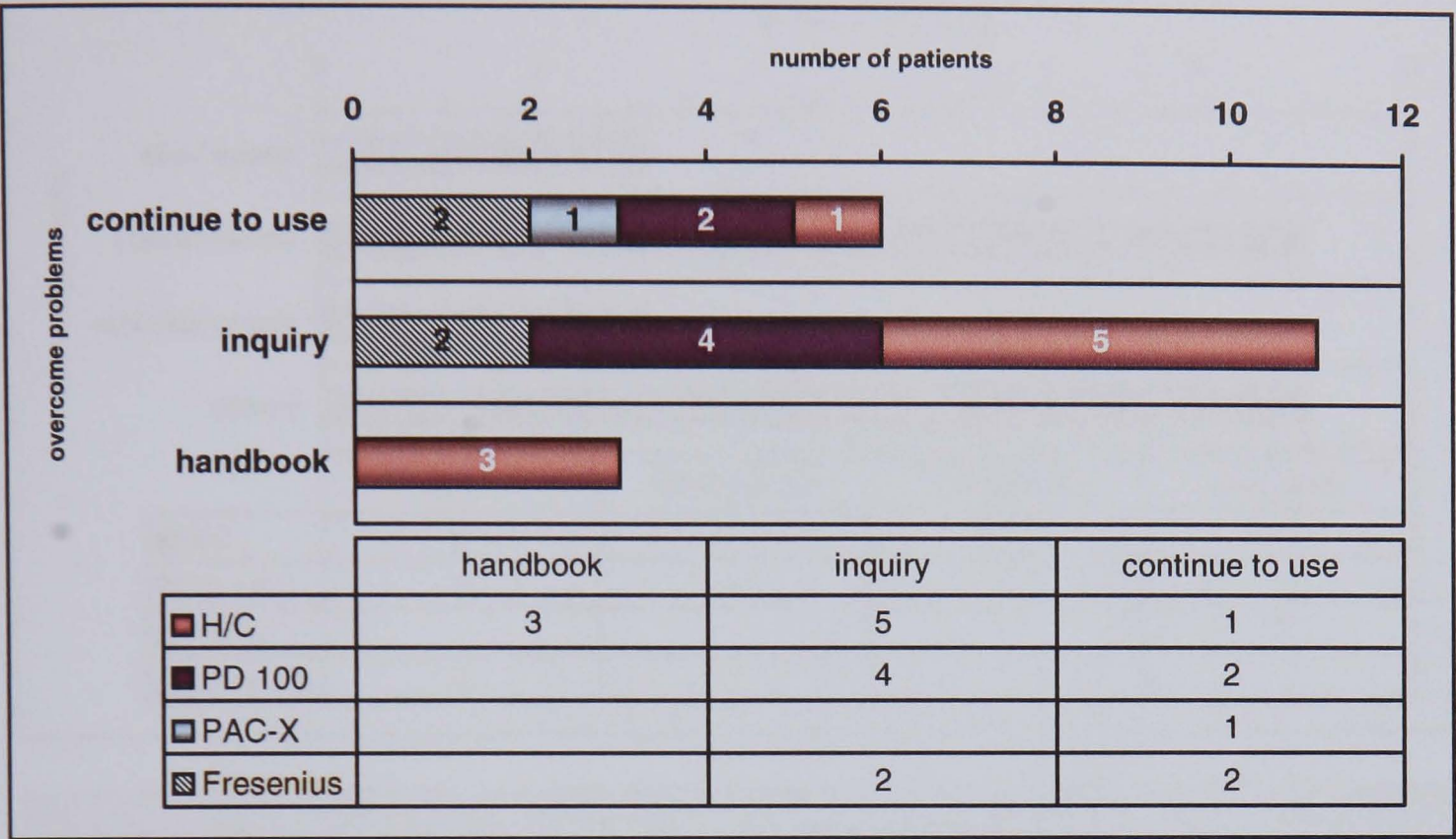


Respondents	Other comments
H/C: 2	Storage/ faulty cassettes
PD 100: 1	Lifting 15 litres of liquid waste to pour down the toilet / spigot that connects tubes is plastic links on machine, it's too small and blocks very easily with fibrin on CCPD machine with the bags CAPD instead of using loose blue clamps, the small white clamps used on CCPD bags could be fitted showing a large saving on packing and storage.
Fresenius : 1	Alarm ringing 5 times a night, lower clamps failing to engage/ shut off tubes. Handbook- difficult to understand

20 respondents provided 27 ticks and other comments, among them, 40.7% ticks referred to problems with set up, 33.3% of ticks referred to problems with control, 11.1% of ticks to problems with maintenance, 14.8% referred to other problems, as seen in the above table. 8 respondents (H/C: 3, PD 100: 4 and PAC-X: 1) answered that they had experienced no problems.

Q6. How did you overcome these problems?

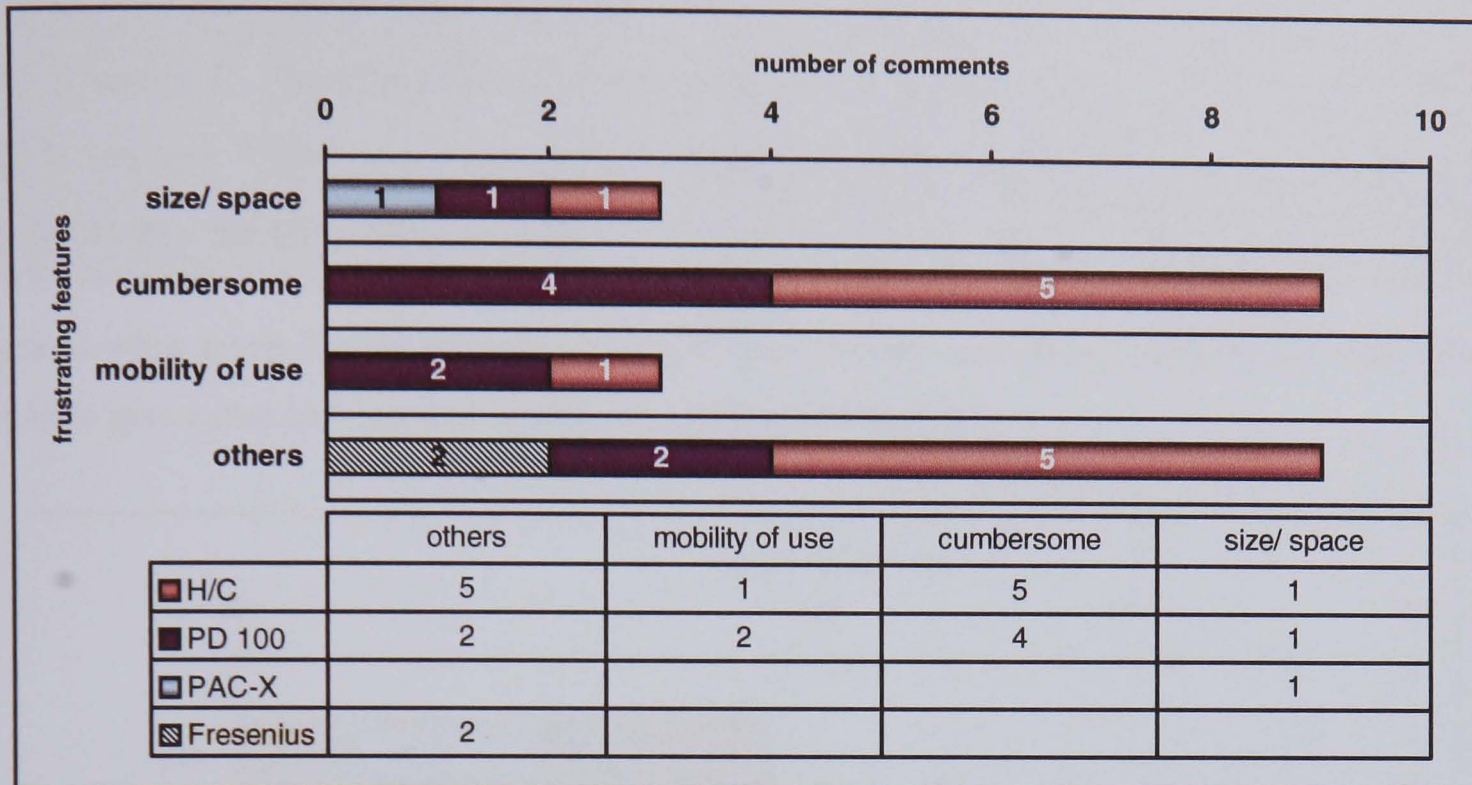
No options were given.



Content analysis was used to explore the answers. 20 respondents answered in addition to Q5, 30% of respondents answered that they had continued to use the equipment, with practice and experience, 55% of respondents had made inquiries from technicians, nurses and manufacturers and only 3 respondents had referred to handbooks or manuals. There are many types of manuals and handbooks but those are difficult to understand, especially in an emergency. One user of the Fresenius complained that he had received a letter from Fresenius saying modification of lower clamps would occur but nothing happened and he used to sit up 5 times a night trying to solve the problem. Clearly, there are opportunities for improved design.

Q15. What is the most frustrating feature of your equipment?

No options were given.



Respondents	Other comments
H/C: 2	Sleep disturbance
H/C: 1	Fluid bags are too heavy
H/C: 2	Takes a long time for dialysis
H/C: 1	Having to sleep with a tube attached from me to a machine and setting the equipment up day in/ day out every day of the year, affects social life
PD 100: 1	Having to go to bed at 10 o'clock to be finished by 8:30 am and not being able to go to the toilet
H/C: 1	Not knowing how to cope when machine needs adjustment, through lack of understanding. Need more tuition when you are not used to computers.
PAC-X: 2, Fresenius: 1	Gravity (having to be higher than the drainage bag, which means an extra mattress on the bed)
H/C: 2, Fresenius: 1	Alarm
Fresenius: 1	Malfunction

This was an open-ended question and content analysis was used to explore the answers. 20 respondents provided 24 answers and other comments, among them, 12.5% of answers related to size and space, 37.5% to cumbersome, 12.5% to mobility of use and 37.5% were other comments as above. 8 respondents (H/C: 3, PD 100: 4 and PAC-X: 1) did not answer.

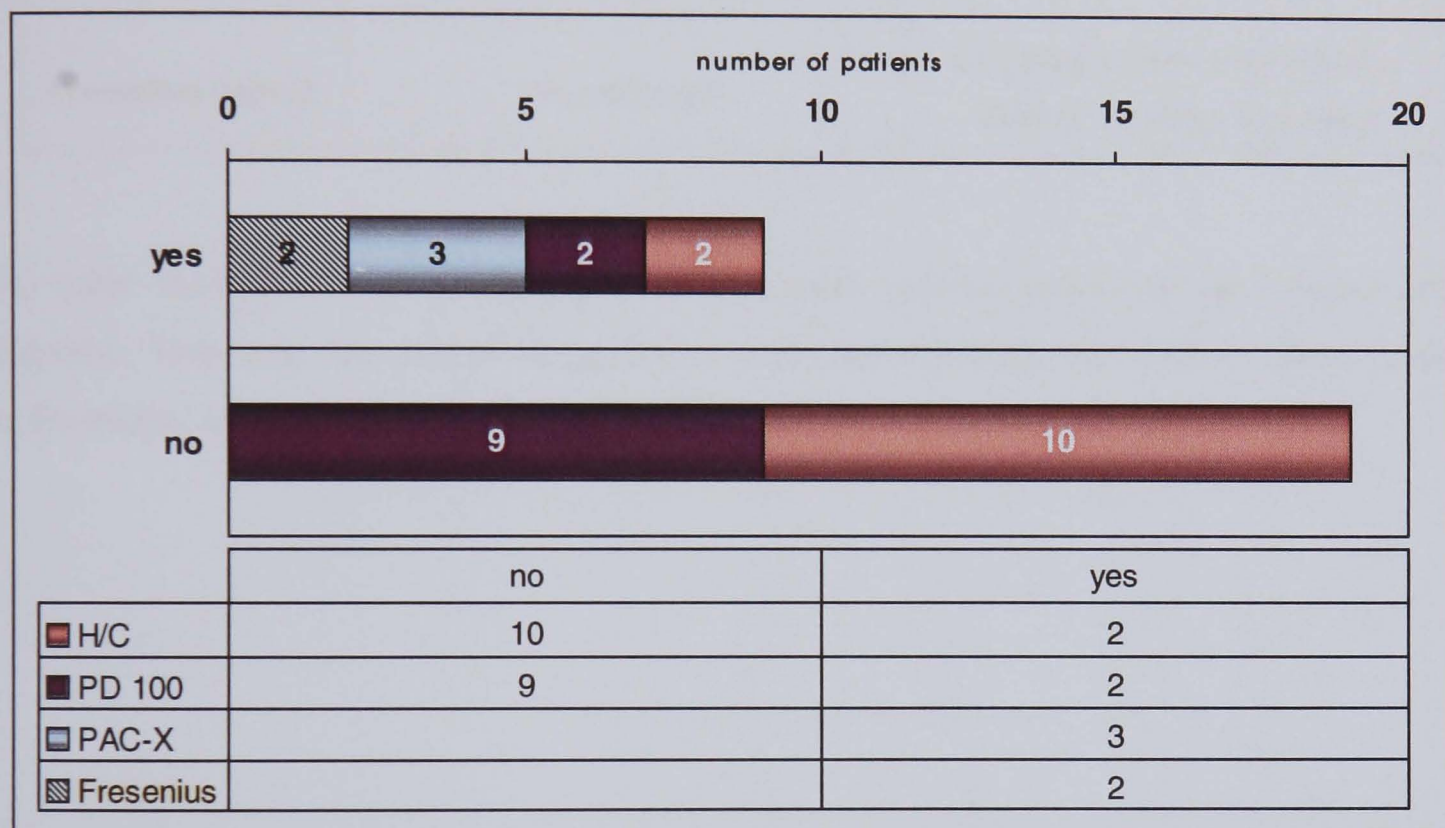
Objective 5. To identify opinions about availability/ loan/ ownership.

Q7. Do you know of any different (or better) equipment?

Q8. If yes to 7. Please give product names & types.

Q9. If yes to 7. What do you consider is better about this equipment in comparison with what you are currently using?

Options were given for the respondent to tick 'yes' or 'no' and then if 'yes' to Q7 they were asked to give name and types of equipment and then answer Q9.



32.1% of respondents answered 'yes' and 67.9% of respondents answered 'no'.

Many other types of peritoneal dialysis are available and information is also available. However, the respondents to this survey were restricted by lack of personal finance and access to information other than that obtained from nurses and other patients.

The information given to the patients is limited. Even though some other new equipment is available it is not possible to use with their illness. Obviously peritoneal dialysis is cheaper than haemo dialysis but still expensive to buy. On the other hand, some way of financing could be found so that patients do not need to buy equipment themselves.

The following table gives product names & types and the respondents comments.

Current use	Different equipment	Comments
H/C user: 1	Fresenius Home dialysis system	Cheaper to run but know nothing of its working
H/C user: 1	PAC-X dialysis machine	Nothing better - bigger & not portable
PD 100 user: 1	AMP 90 cycle machine	More up to date but not better
PD 100 user: 1	Using salt for waste softener	Currently using is better
PAC-X user: 3	HomeChoice/ Homecare/ Home start	Portable & much smaller
Fresenius user: 2	HomeChoice	Clamping system held with in a disposal cartridge & portable

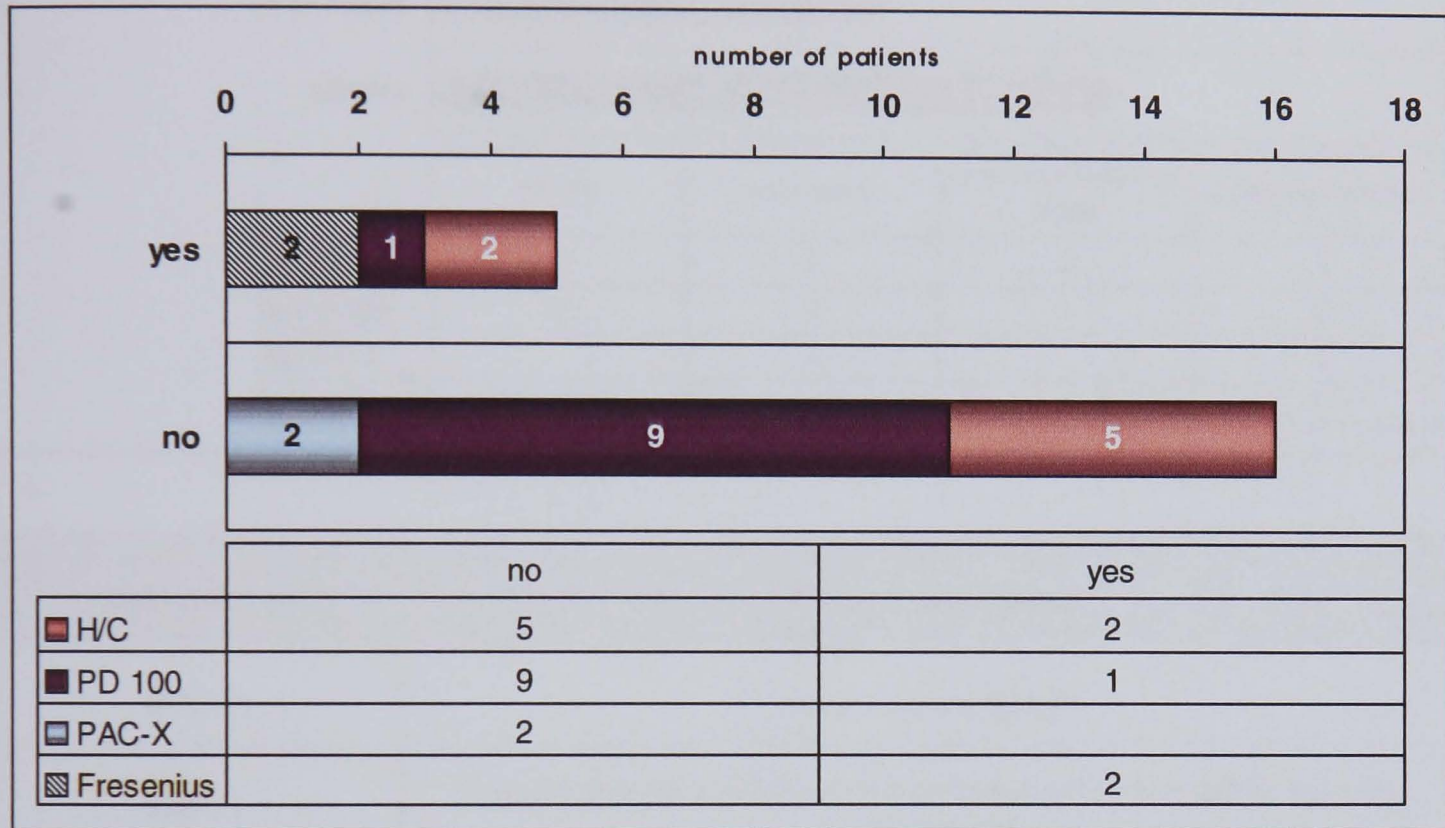
This table show that some users prefer to use more modern equipment and expect better treatment. However, one user of HomeChoice preferred to use an older style product, namely, the Fresenius, since he said it was cheaper to run.

Objective 6. To identify opinions about any possible improvement.

Q13. Do you think there is a need for any other home-care treatments, if suitable equipment and help is provided?

Q14. If yes to 13. Can you suggest any examples?

Options were given for the respondent to tick 'yes' or 'no' and then if 'yes' to Q13 they were asked to suggest any examples.

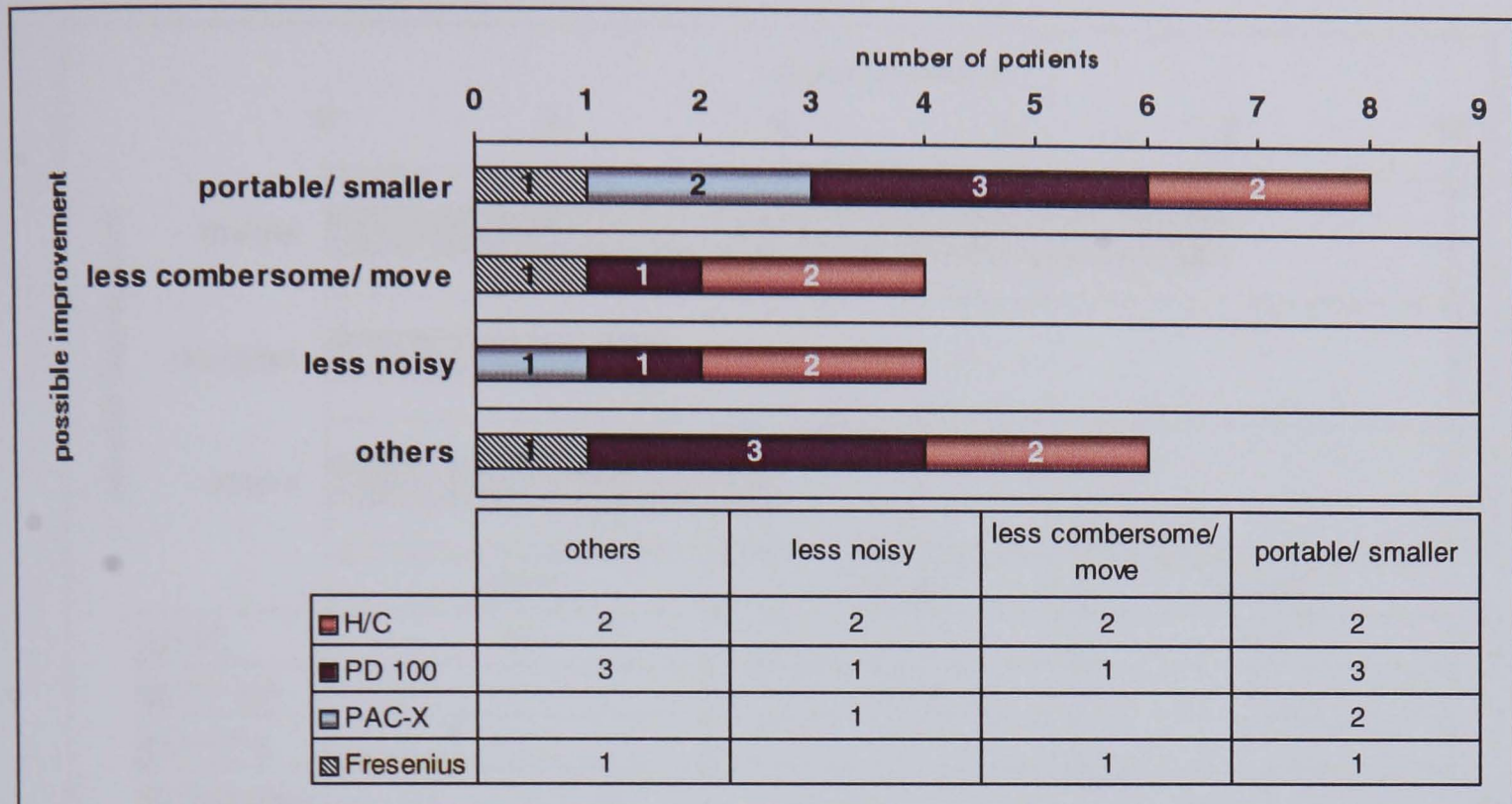


Respondents	Examples
H/C : 1	Breathing & infusion
PD 100 : 1	Plugged in car for travelling
Fresenius:1	Blood sample equipment
H/C: 1, Fresenius: 1	Unanswered

21 respondents provided 21 ticks. 23.8% of ticks were 'yes', 76.2% of them were 'no'. 7 respondents (H/C: 5, PD 100: 1 and PAC-X: 1) did not answer. Three patients think it might be good if other equipment could be available and there could be a design opportunity with benefits to other areas.

Q17. Could your equipment be improved & how?

No options were given.

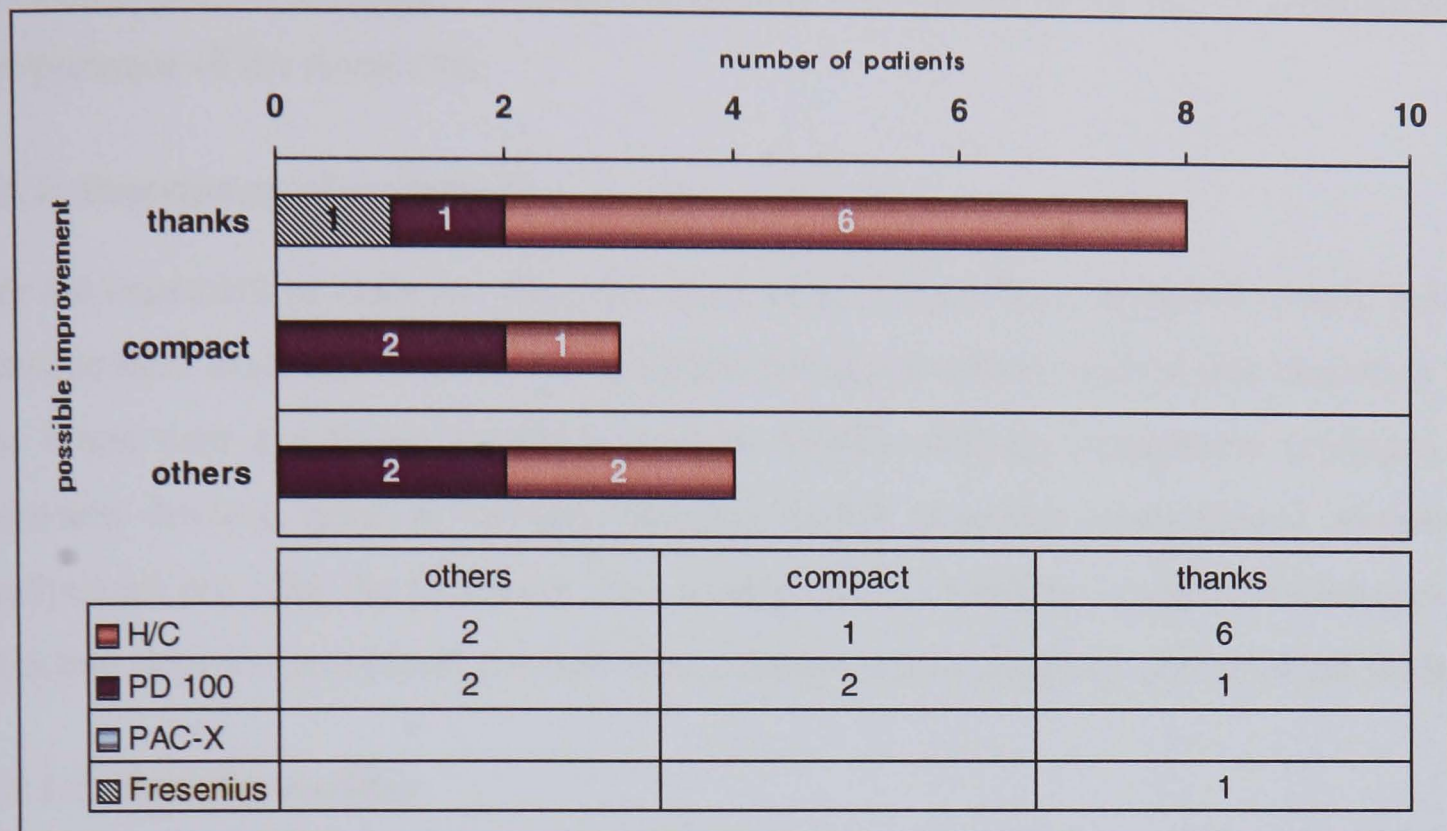


Respondents	Other suggestions
H/C : 1	Less time for dialysis
H/C : 1	It could provide a print-out to take to the consultant rather than the record book
PD 100 : 1	Out door use/ easy connection/ flexible
Fresenius:1	Make it small and accessible to use by blind

This was an open-ended question and content analysis was used to explore the answers. 20 respondents provided 22 suggestions. 36.3% of answers related to making more portable and smaller, 18.2% referred to less cumbersome, 18.2% to less noisy, 27.2% referred to other answers as shown in the above table. 8 respondents (H/C: 4, PD 100: 3 and PAC-X: 1) did not answer.

Q18. Is there anything more you would like to say about the equipment you use?

No options were given.



Respondents	Product names & types
H/C : 1	I worry about the expensive accessories required to run the machine & the waste (mainly plastic)
H/C : 1	We feel very lucky & pleased to have a HomeChoice. We feel a video-cassette would be useful for people like ourselves who through lack of knowledge feel almost frightened of the machine when you first have problems.
PD 100 : 1	The connection from the cyclor set to the 2.5 litre drainbags needs to be the other way round as it is likely to block with fibrin.

This was an open-ended question and content analysis was used to explore the answers. 15 respondents provided suggestions. Among the 15 respondents, 53.3% of answers related to express their thanks to having it, 20% referred to expecting more compact equipment, 26.6% of answers referred to the other answers as in the above table. 13 respondents (H/C: 3, PD 100: 6, PAC-X: 3 and Fresenius: 1) did not answer.

4.5 Diabetic unit product user survey

This section provides the analysis of a questionnaire survey at the Diabetics Unit of Leicester General Hospital. The questionnaires were filled in by the 30 respondents in the presence of the researcher.

4.5.1 Description of equipment

For the treatment of diabetes, there are more than 200 products designed to help patients manage their diabetes. The study identified that the products used in this Diabetics Unit for home care are finger pricking devices, insulin delivery equipment (syringes and injection devices, pens & needles, pumps), blood glucose meters (blood monitoring equipment) etc. For the Diabetics Unit survey, insulin delivery equipment (syringes and injection devices) and blood glucose meters (blood monitoring equipment) were studied.

4.5.1.1 Diabetes mellitus

Diabetes mellitus is an illness or metabolic disorder in which the body is not able to make proper use of food consumed due to a lack or insufficiency of insulin production. Insulin, produced by the pancreas, is vital in the metabolism and assimilation of glucose into the body. Without the proper amount of insulin, glucose cannot be utilised by the body as a source of energy. When the glucose is not absorbed by the body, it remains in the blood, eventually spills into the urine and is eliminated from the body (Burden, 1995).

4.5.1.2 Function of insulin in relation to glucose

Glucose is the primary fuel for all body tissues. The brain uses about 25% of the total body glucose. However, because the brain can store very little glucose, a constant but controlled supply of glucose must always be available in the bloodstream to maintain adequate brain function. It is imperative that the blood glucose level be maintained in the 60 to 120 mg/dL range to prevent nervous system compromise (American Diabetes Association, 1996; Eli Lilly, 1997).

Insulin is the primary hormone for regulating blood glucose levels. It accomplishes this function by controlling the rate at which glucose is taken up in muscle, fat, and liver cells. Each of these types of body cells use glucose in a different way, as determined by specific enzyme systems.

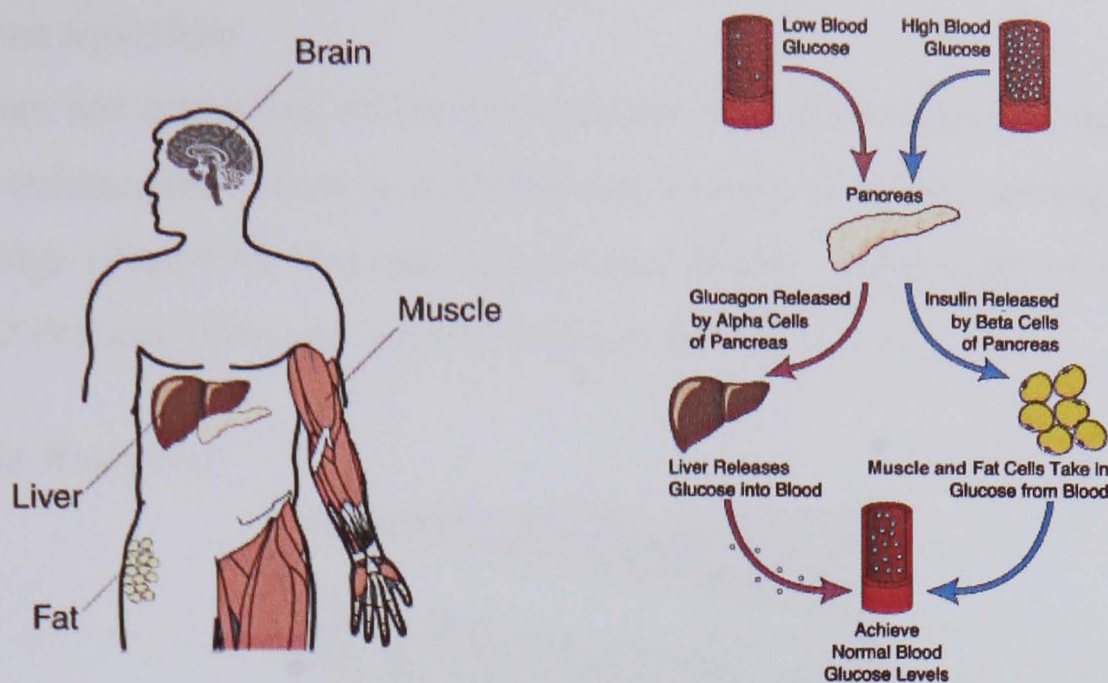


Figure 4-10. Production of endogenous insulin (Eli Lilly, 1997)

The management of diabetes is based on the interaction of insulin and other hormones with the cellular processes of these three types of body cells. Glucose is the primary stimulus to insulin release. Even if, at first, there is only a partial lack of insulin, unfortunately this can progress to a total lack of insulin (Burden, 1995; Eli Lilly, 1997).

4.5.1.3 Insulin delivery equipment

The types of equipment used in the Diabetes Unit survey are categorised as syringes, pen injectors and monitoring systems with finger pricking devices.

Syringes

This survey included disposable syringes which include Becton Dickinson insulin syringes. Disposable syringes are made either of glass or plastic and can be used as long as the needles stay sharp. Needles can be stored in their packets along with insulin in the fridge (Becton & Dickinson).

Becton Dickinson insulin syringes



Figure 4-11. Becton Dickinson insulin syringes

The BD models are in capacities 0.3ml, 0.5ml and 1.0ml. The needle and the syringe are thrown away after one use.

Alternative pen injections

An insulin pen has something of the convenience of a traditional cartridge pen - only instead of a writing point, there is a needle, and instead of an ink cartridge, there is an insulin cartridge (American Diabetes Association, 1996). Three types of pen injectors, Humulin, BD Pen and Novopen, were included as follows: -

Lilly Humulin-HumaJect



Figure 4-12. Lilly Humulin-HumaJect

Humulin is the name for a biosynthetic human insulin made by Lilly. This is supplied in three forms, cartridges, vials and pre-filled pens. Cartridges are used with the BD pen devices. Vials are used with insulin syringes. HumaJect is the name for pen type injector which has different types and those are mixed with 6 different pre-filled insulin (HumaJect Catalogue, 1995).

Becton Dickinson Pen

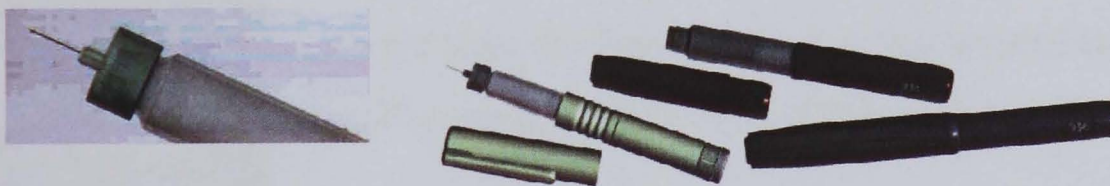


Figure 4-13. Becton Dickinson Pen

There are three types of pens available which their dose adjustments up to 30 units, 59 units and 69 units. All insulin delivery pens feature an audible click during dose setting and injection (Becton Dickinson).

Novopen

Novopen I is an insulin delivery device which delivers in 2 unit increments (Diabetes UK, 1997).

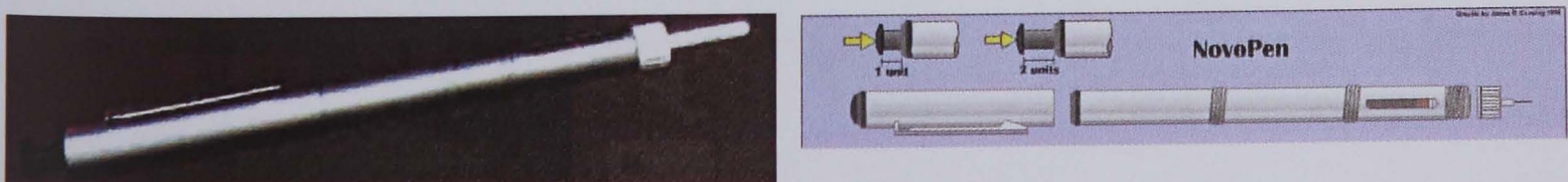


Figure 4-14. Novopen

Novo 1.5 is a stainless steel and matt black insulin delivery device which features a dial-a dose facility and delivers from 1-40 units in increments of 1 unit (Diabetes UK, 1997).

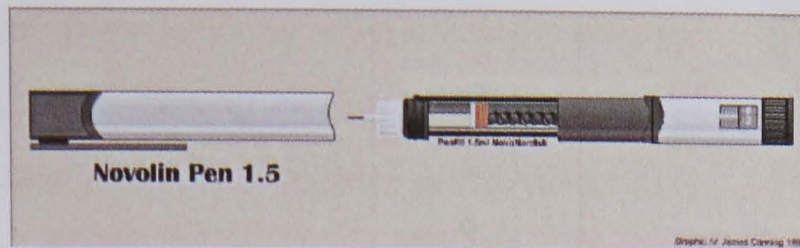


Figure 4-15. Novopen 1.5

Novo II is an insulin delivery device which features a dial – dose facility and delivers from 2-36 units in increments of 2 units. This pen is not suitable for use by the visually-impaired (blind or near blind) diabetics unless they are assisted by a sighted person trained in the use of this device (Diabetes UK, 1997).

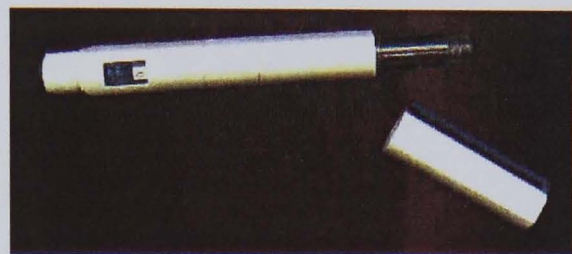
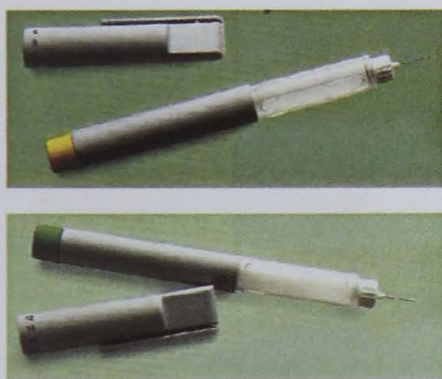


Figure 4-16. Novopen II



The Novopen 3.0 uses a 3.0 ml cartridge and provides 300 units of insulin. The Novopen 3 is only slightly larger than the Novopen 1.5 and is available in Classic or Fun design and colours (Diabetes UK, 1997).

Figure 4-17. Novopen 3.0

Monitoring system with finger pricking device

Blood glucose meters, or so called lancets or monitoring systems, measure blood sugar. These monitoring systems can store the test results and other information (depending on the system) such as glucose level, time, date, insulin type and dose (American Diabetes Association, 1997). The monitoring systems included 'One touch II', 'Accutrend', 'Rofloux' and 'Glucometer'. A finger pricking device is frequently provided as part of a blood glucose meter.

Ames Glucolet

Glucolet is a pocket finger pricking device supplied with lancets. The glucolet finger pricking device is designed for individual patient self - monitoring. It should not be used on different patients unless the end cap as well as the lancet is discarded after each patient use.

(American Diabetes Association, 1997)



Figure 4-18. Ames Glucolet

Johnson & Johnson One touch II

One touch II is a blood glucose monitoring device. Test strips are available on NHS prescription. Tests start automatically and results appear in 45 seconds. The last test result is stored in a memory (Diabetes UK, 1997).



Figure 4-19. Johnson & Johnson One touch II



Figure 4-20. BM Accutrend

Boehringer Mannheim Accutrend

Accutrend is a blood glucose monitoring system. It gives results in 12 seconds and 50 results can be memorised (BM Accutrend Catalogue, 1996).

Boehringer Mannheim Reflolux

The Reflolux blood glucose meter has a memory facility which can store 20 results. The digital readings appear in 2 minutes and results show date and time (BM Reflolux Catalogue, 1996).



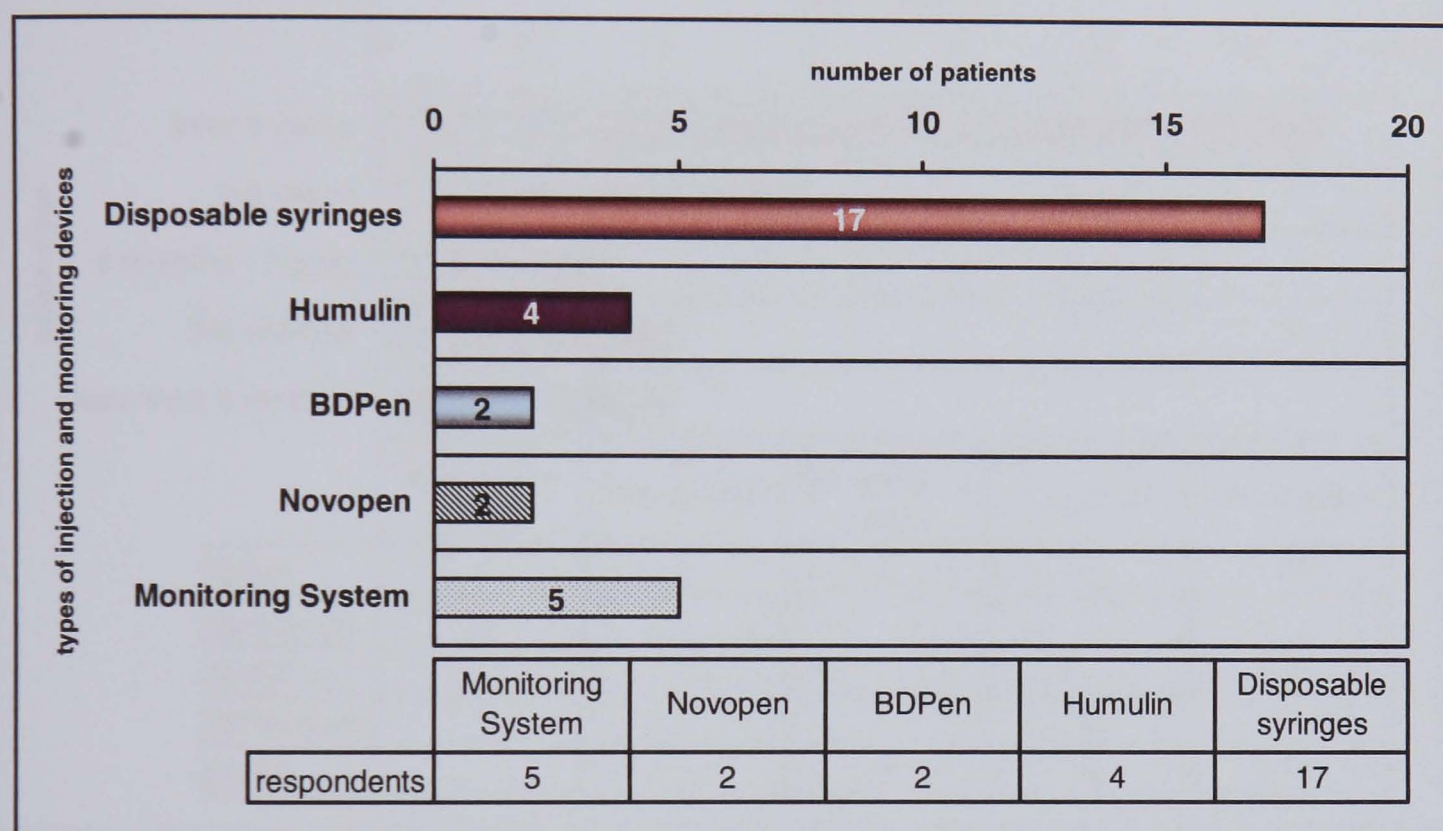
Figure 4-21. BM Reflolux

4.5.2 Results of the diabetic product user questionnaire survey

Objective 1. To identify treatment & equipment types used.

Q1. What types of medical equipment / health-care equipment are you using?

The total number of respondents were thirty patients using different types of injection devices and five of them used blood glucose monitoring devices. The number of patients and the types of equipment are illustrated in the table below; -



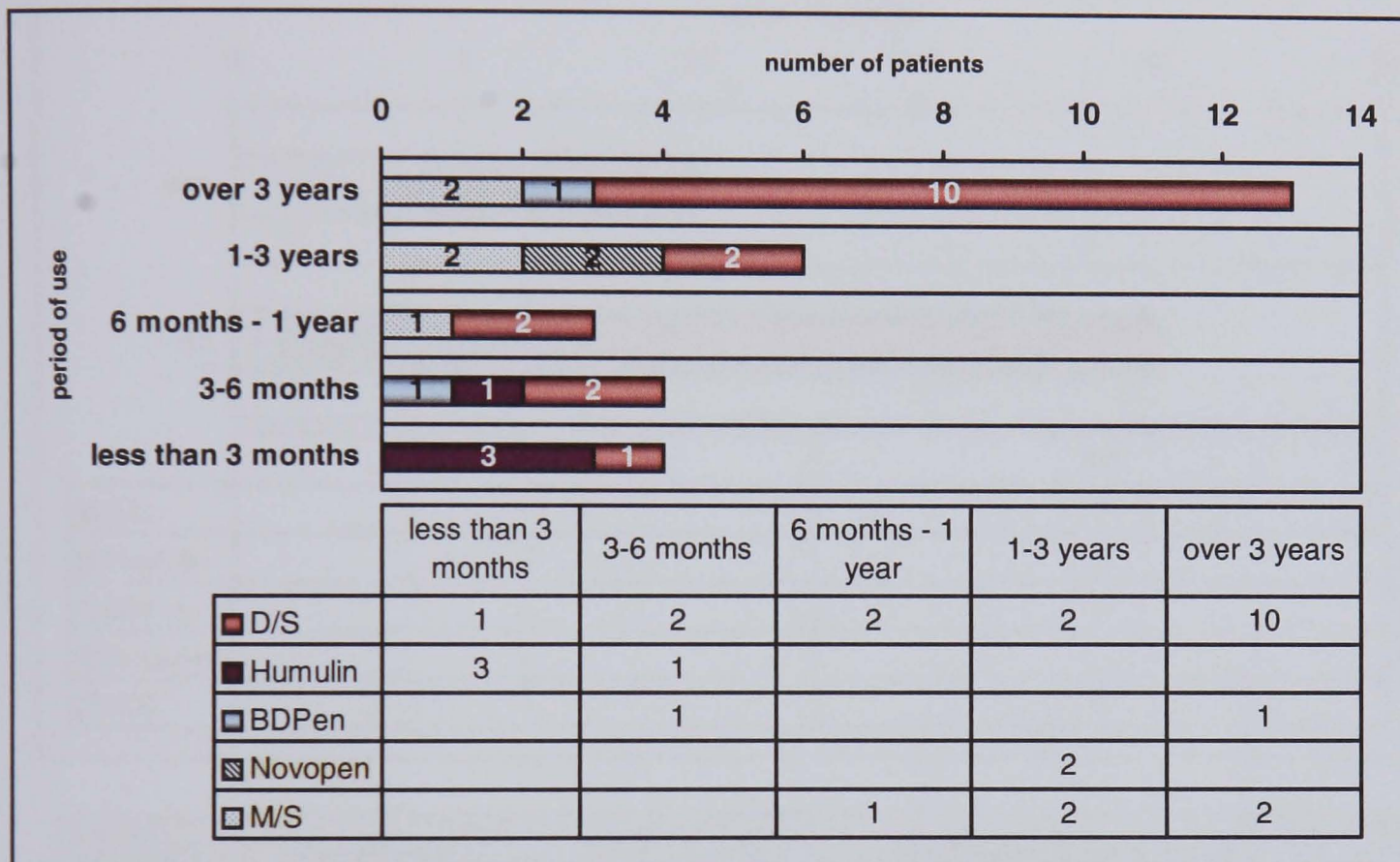
Hospital	Types of injection devices & patients	Types of blood glucose monitoring devices & patients
Leicester General Hospital Renal Unit	D/S: 17, Humulin: 4, BD Pen:2, Novopen: 2	5

56.7% of respondents used Becton Dickinson disposable syringe, 13.3% of respondents used Lilly Humulin-HumaJect, 6.7% of respondents used Becton Dickinson Pen, 6.7% of respondents used Novopen and 16.6% of respondents use blood glucose monitoring devices. The types of blood glucose monitoring devices used in this survey were as follows; two patients used Bayer Diagnostics Glucometer, one patient used Johnson & Johnson One touch II, one patient used Boehringer Mannheim Accutrend and one patient used Boehringer Mannheim Reflolux.

Q2. How long have you been using this equipment?

The following options were available to tick an appropriate answer: -

- less than 3 months
- 3-6 months
- 6 months - 1 year
- 1-3 years
- over 3 years

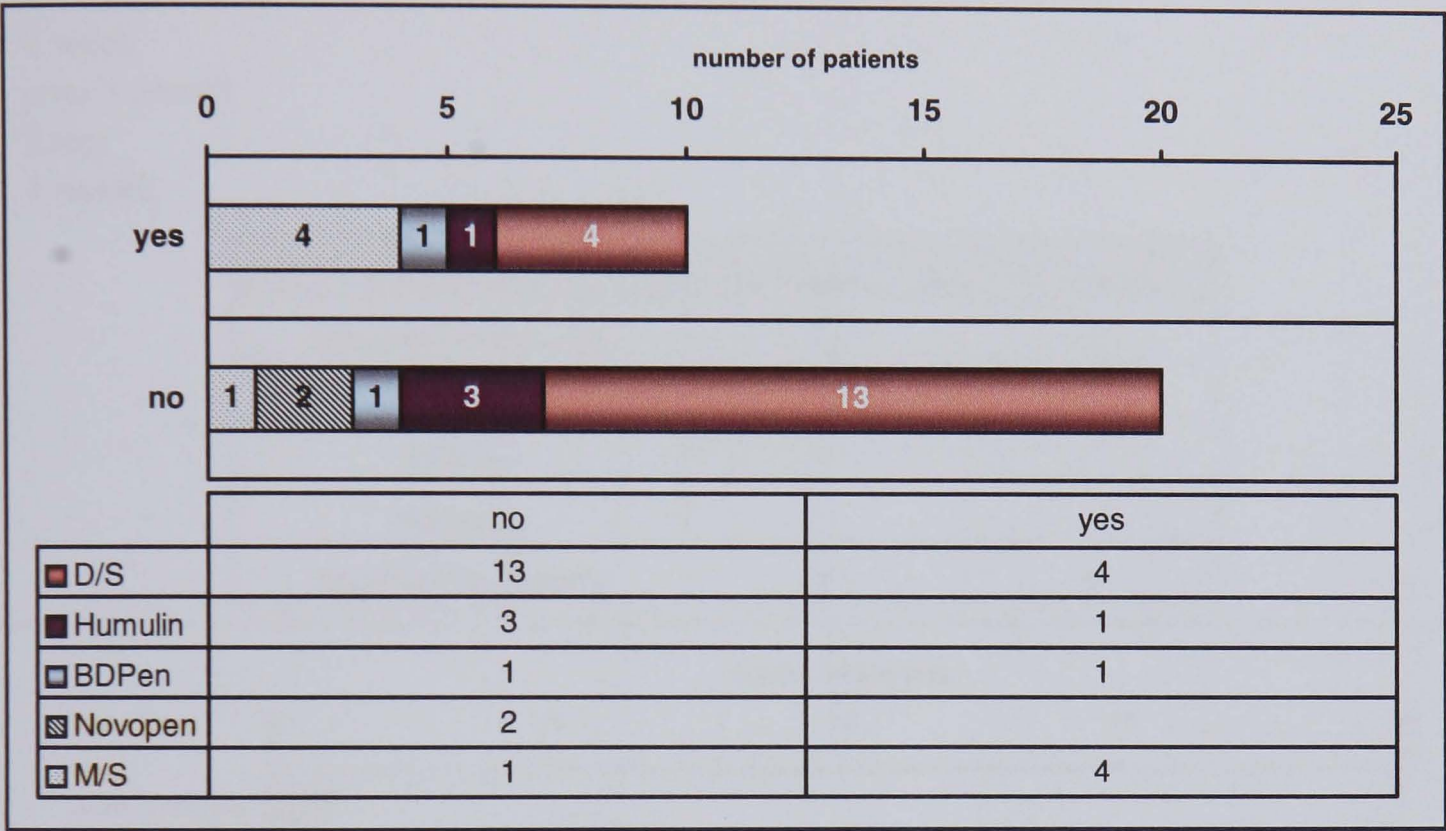


43.3% of respondents had used their equipment for over 3 years and 20% of respondents for 1-3 years, 10% of respondents for 6 months to 1 year, 13.3% of respondents for 3-6 months and 13.3% of respondents had been using their equipment for less than 3 months.

Q15. Do you have any other hospital equipment and home use equipment, related to the same treatment?

Q16. If yes to 15. Please give equipment names & types

The options that were given for the respondents were to tick 'yes' or 'no' and then, if 'yes' to Q15, they were asked to give the name of the equipment and its use.



Respondents	Product names & types
D/S: 4, Humulin: 1, BDPen: 1	Blood glucose meter
D/S: 2, Humulin: 1, M/S: 3	Finger Pricking
M/S: 2	Syringe
M/S: 1	Pen Type Syringe

One third of respondents (33.3%) answered 'yes', and two third of respondents (66.6%) answered 'no'.

Objective 2. To identify the nature of equipment user training.

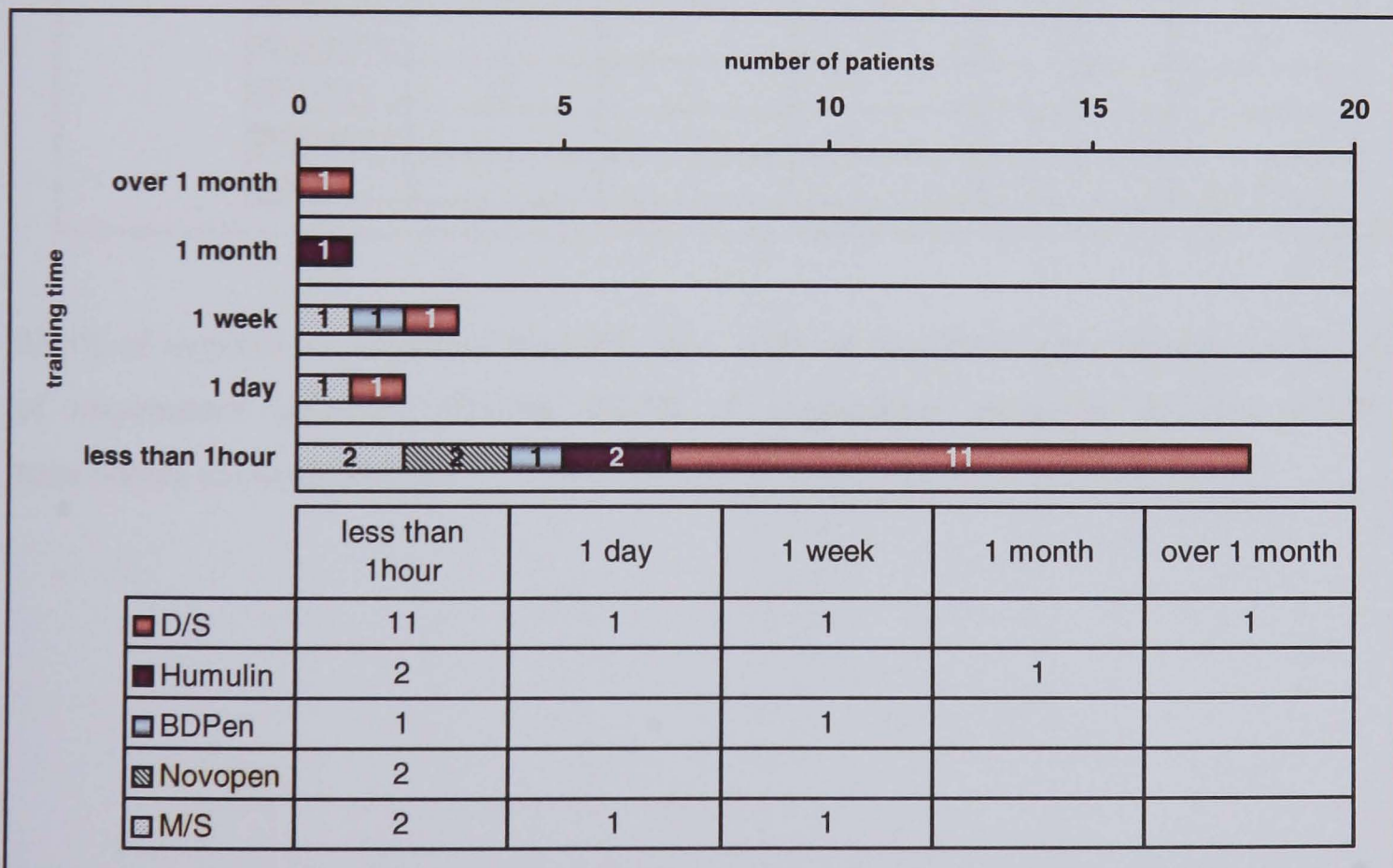
Q3. Have you ever received training before using this equipment?

Q4. If yes to 3. How long were you trained?

The options that were given for the respondents were to tick 'yes' or 'no' and then, if 'yes' to Q3, they were asked for the training time. The following options were available for ticking: -

- less than 1 hour
- 1 week
- over 1 month
- 1 day
- 1 month

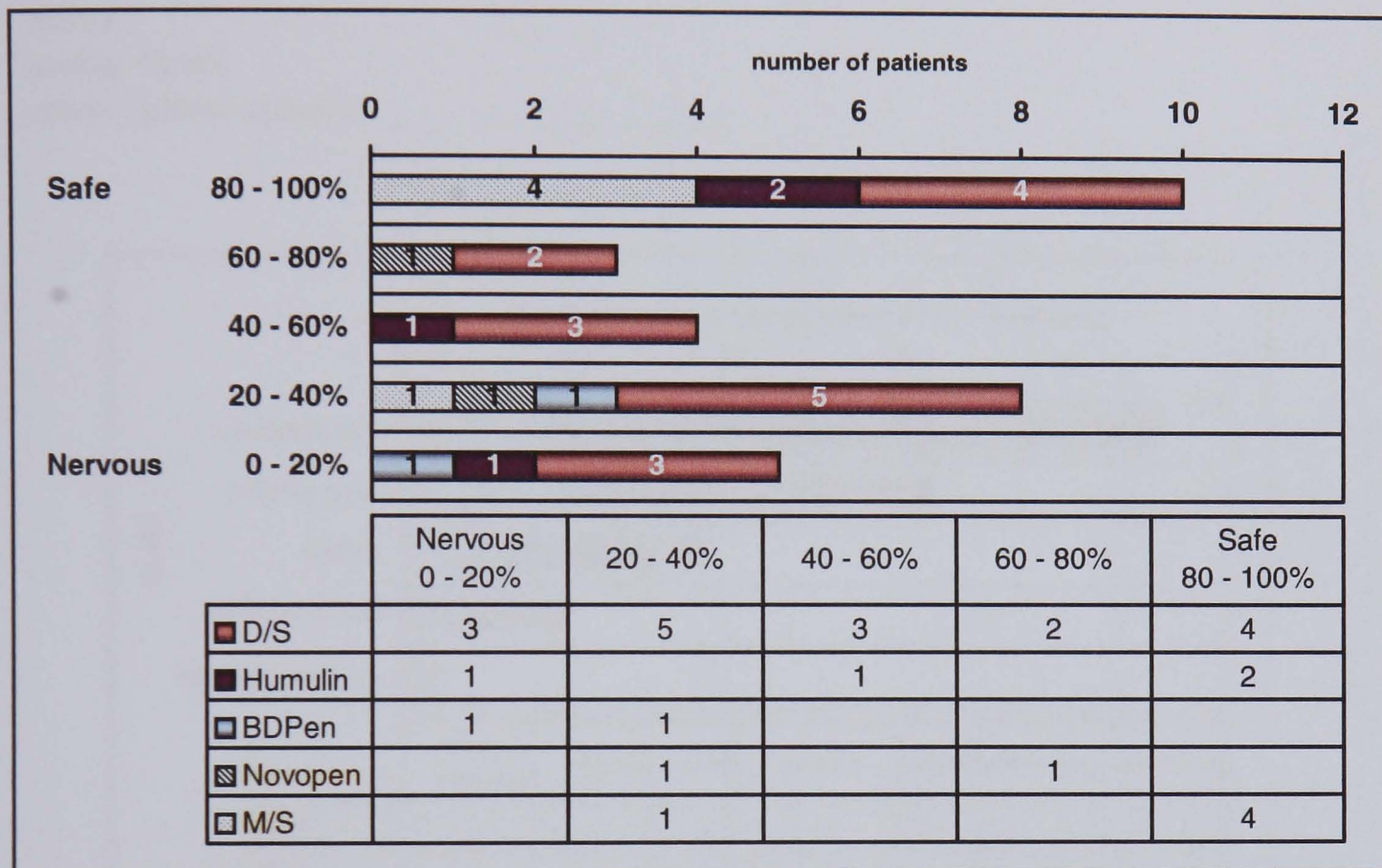
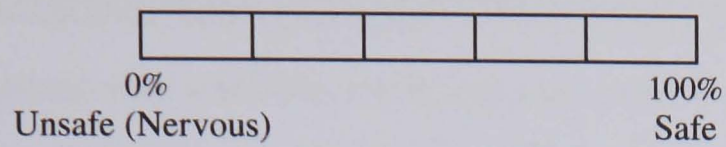
Products	Yes	No
Disposable Syringe	14	3
Humulin	3	1
BDPen	2	
Novopen	2	
Monitoring System	4	1



25 patients had been trained before using the equipment. Among them, one respondent had been trained for over 1 month, one respondent had received training for 1 month, 12% had received training for 1 week, 8% had received training for 1 day and 72% of respondents had received training for less than 1 hour. Therefore, the vast majority (83.3%) of users had received training before home use of less than an hour.

Q5. When you first used this equipment, how did you feel about it?

The following five point scale options were available for ticking: -



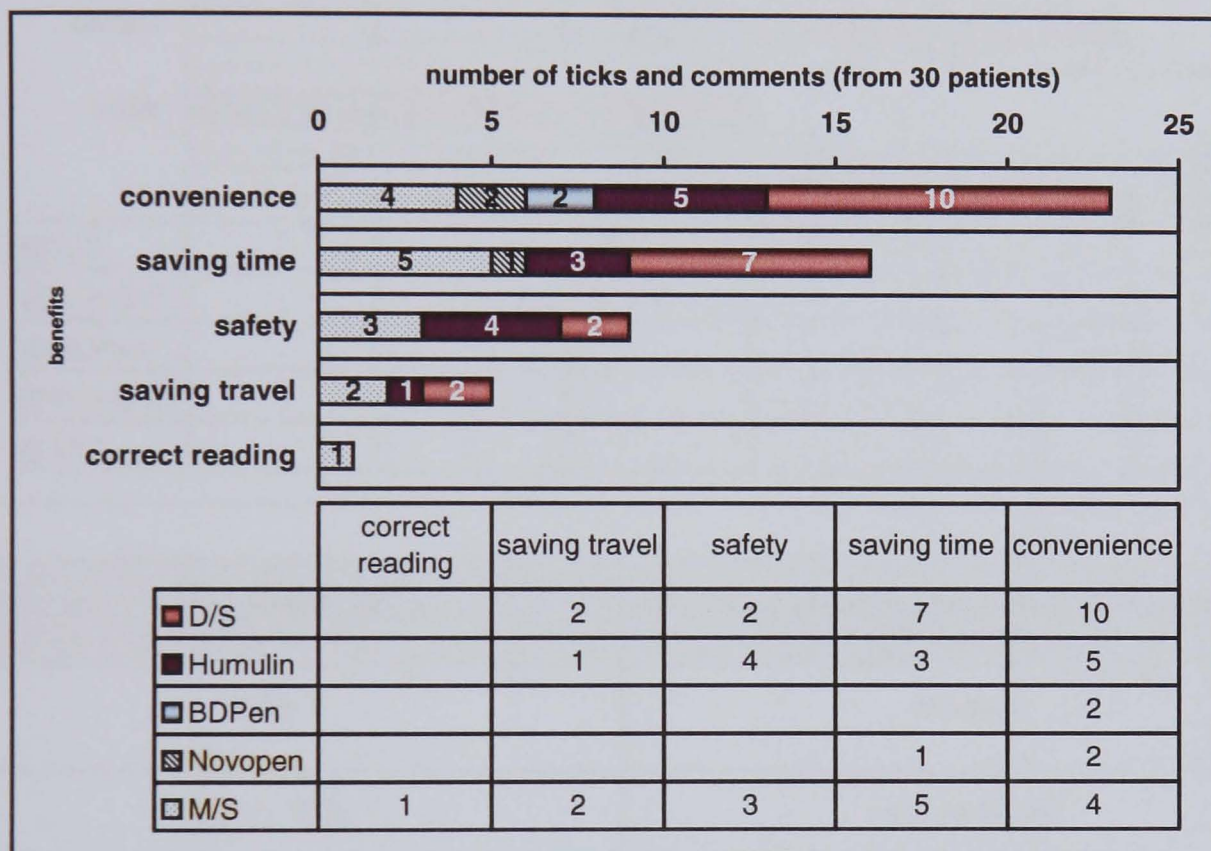
33.3% of respondents answered 80-100% safe. 10% of respondents answered 60-80%, 13.3% of respondents answered 40-60%, 26.7% of respondents answered 20-40%, 16.7% of respondents answered 0-20%.

Objective 3. To identify opinions about benefits of use.

Q14. What are the benefits of using this product at home?

The following options were available to tick appropriate answer: -

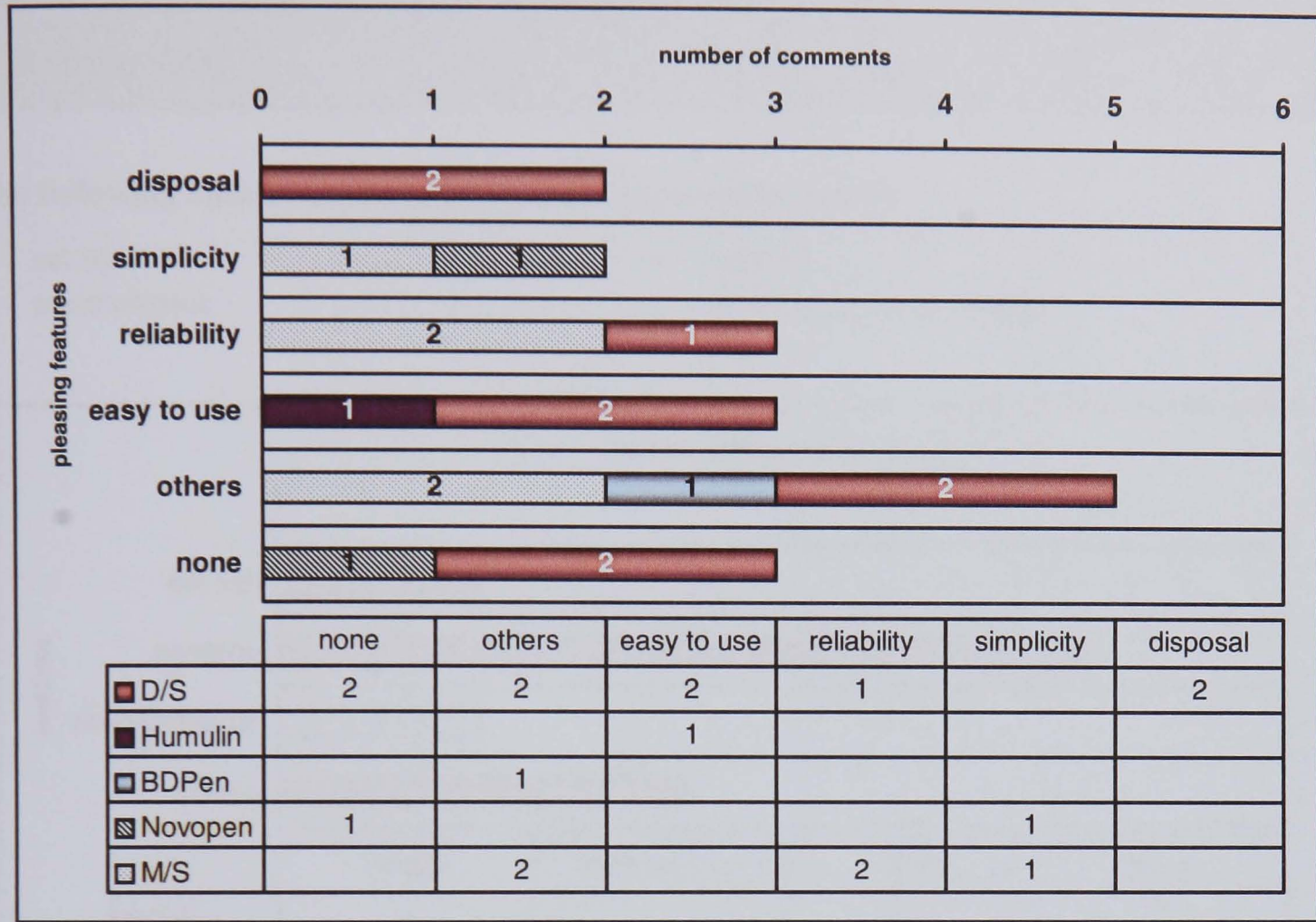
- convenience
- saving time
- safety
- saving travel
- others (please specify) _____.



30 respondents provided 54 ticks and other comments. 42.6% of ticks related to convenience, 29.6% of ticks related to saving time, 16.7% of ticks to safety, 9.3% of ticks related to saving travel as a benefit and one answer was that it gave a correct reading.

Q20. What is the most pleasing feature of your equipment?

No options were given.



Respondents	Other pleasing feature & comments
D/S: 1	No pain
D/S: 1, M/S: 1	Good result
BDPen	Easy to carry
M/S: 1	Connect to computer

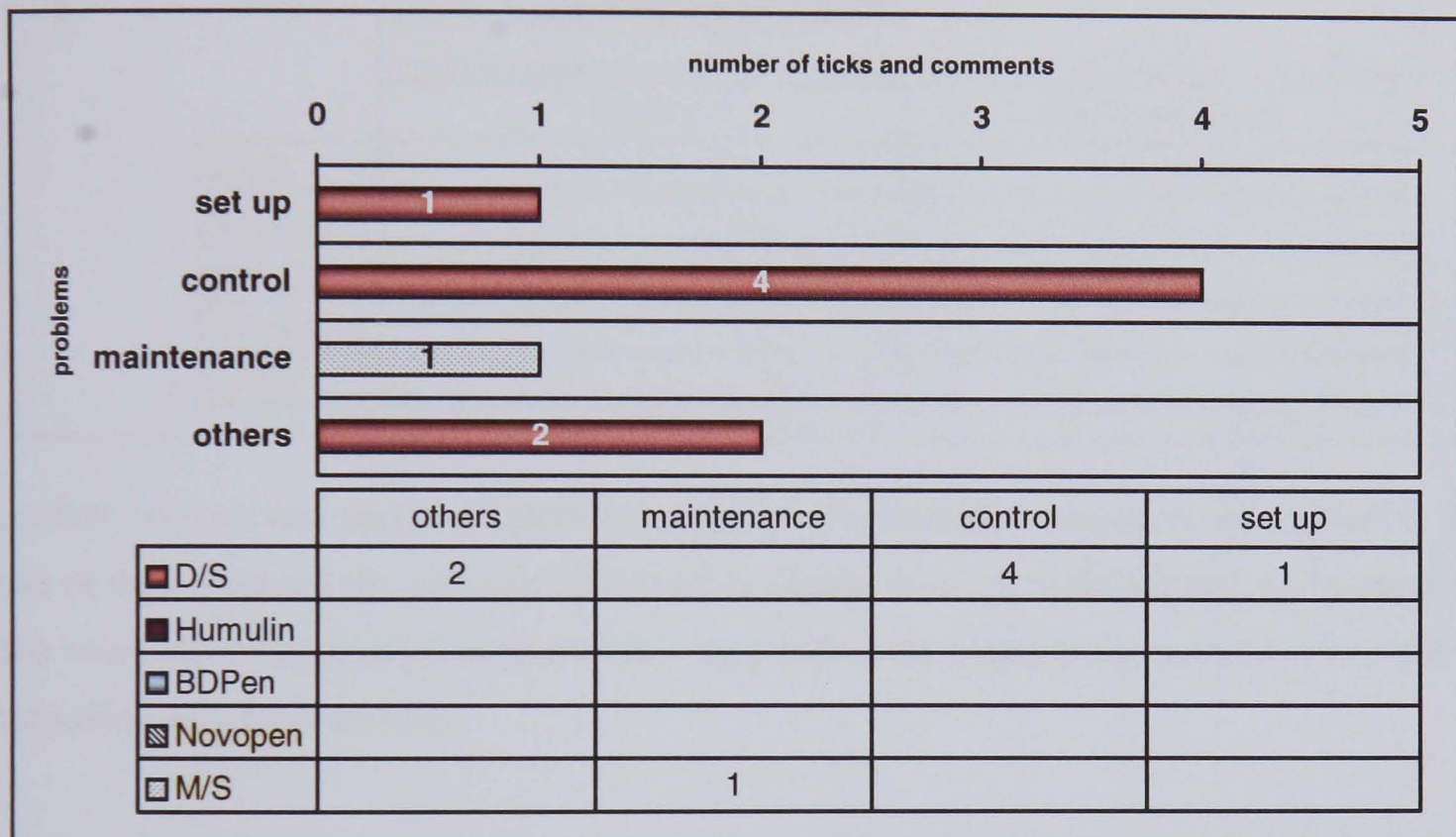
This was an open-ended question with varieties of answers and content analysis was used to explore the answers. 18 respondents answered, among whom, 16.6% mentioned reliability, 16.6% referred to ease of use, 11.1% to simplicity, 11.1% to disposal, 27.8% were other comments as given above and 16.6% said that there were no pleasing feature. 12 respondents (D/S: 8, Humulin: 3 and BD Pen: 1) did not answer.

Objective 4. To identify opinions about problems of use.

Q6. When you first used this equipment, did you have problems with any of the following?

The following options were available to tick appropriate answers: -

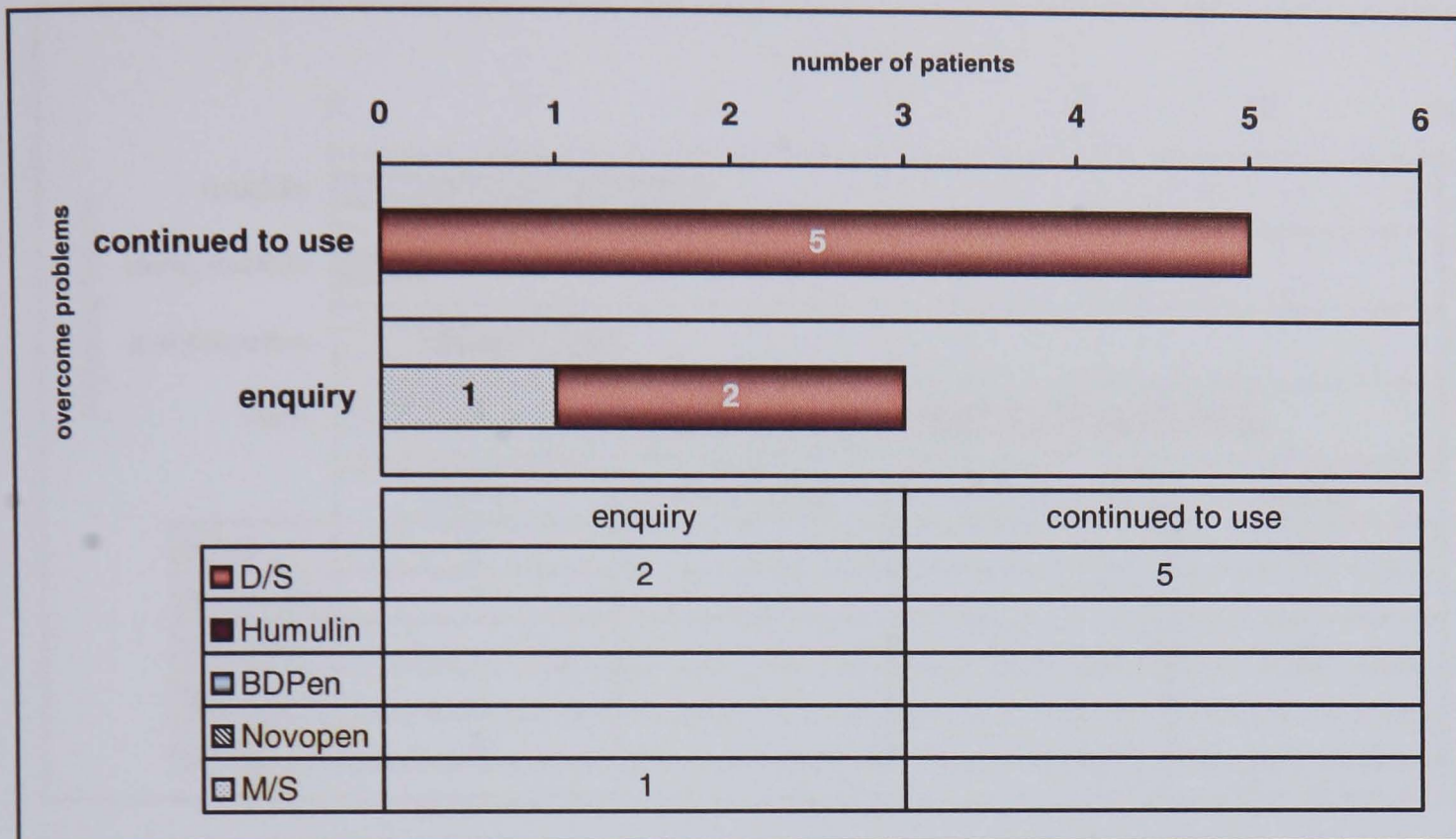
- set up
- maintenance
- control
- or others (please specify)



8 respondents answered, 4 respondents ticked control, one respondent ticked set up, one respondent ticked maintenance, two respondents commented on other things such as having had a 'funny feeling' and double vision. 22 respondents (D/S: 10, Humulin: 4, BD Pen: 2, Novopen: 2 and M/S: 4) answered that they had experienced no problems when first using their equipment.

Q7. How did you overcome these problems?

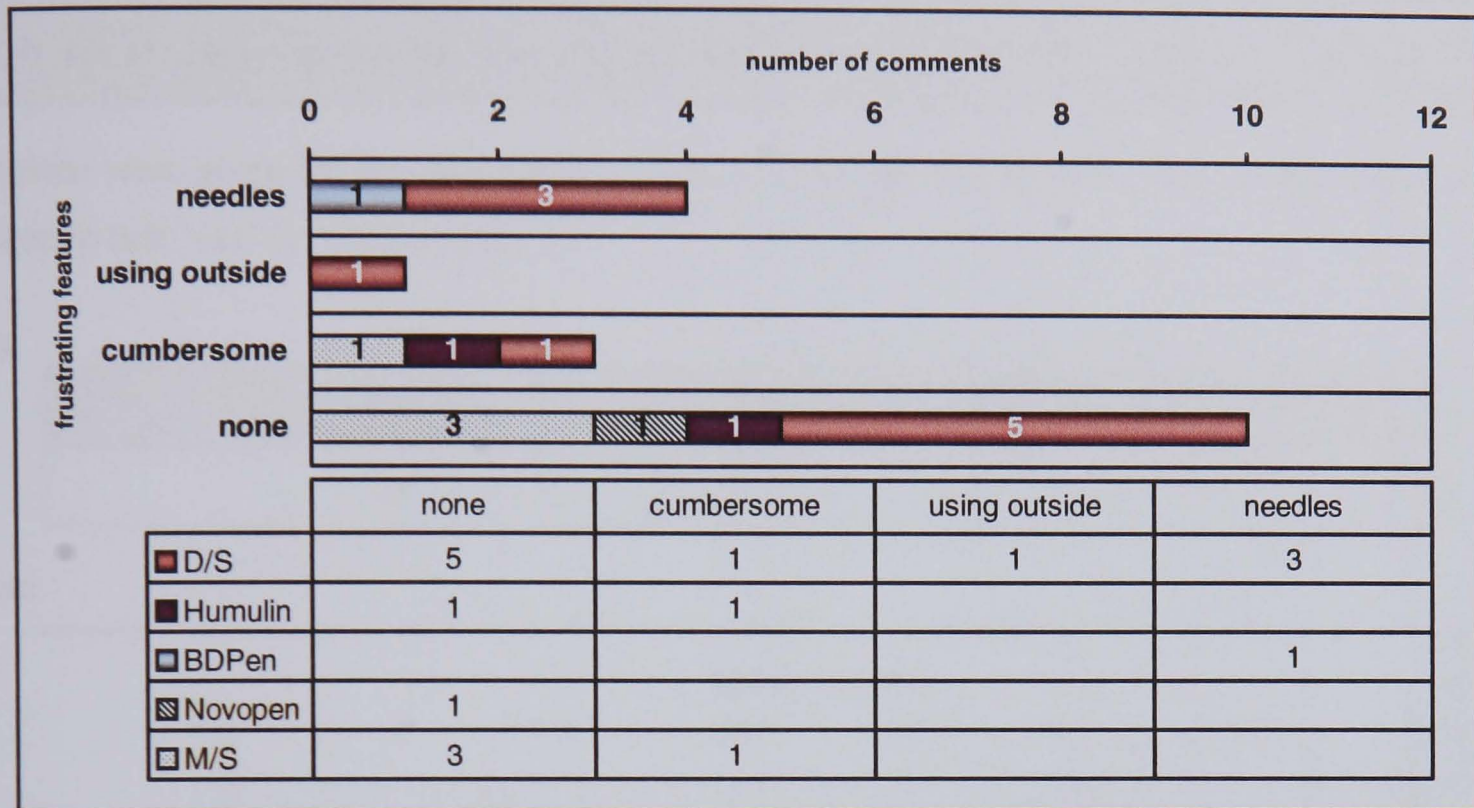
No options were given.



Content analysis was used to explore the answers. 8 respondents answered in addition to Q6, five of these respondents, answered they had continued to use it, with practice and experience. The other three respondents answered that they had made enquiries to manufacturers and by consulting with their hospital.

Q19. What is the most frustrating and annoying feature of your equipment?

No options were given.



This was an open-ended question and content analysis was used to explore the answers. 18 respondents answered. 22.2% of answers related to needles, injecting and pricking a finger to get enough blood to test, 16.7% referred to cumbersome and one answer was using it outside and 55.6% of answers said that there was no frustrating or annoying feature of their equipment. 12 respondents (D/S: 7, Humulin: 2, BD Pen: 1, Novopen: 1 and M/S: 1) did not answer.

Objective 5. To identify opinions about availability/ loan/ ownership.

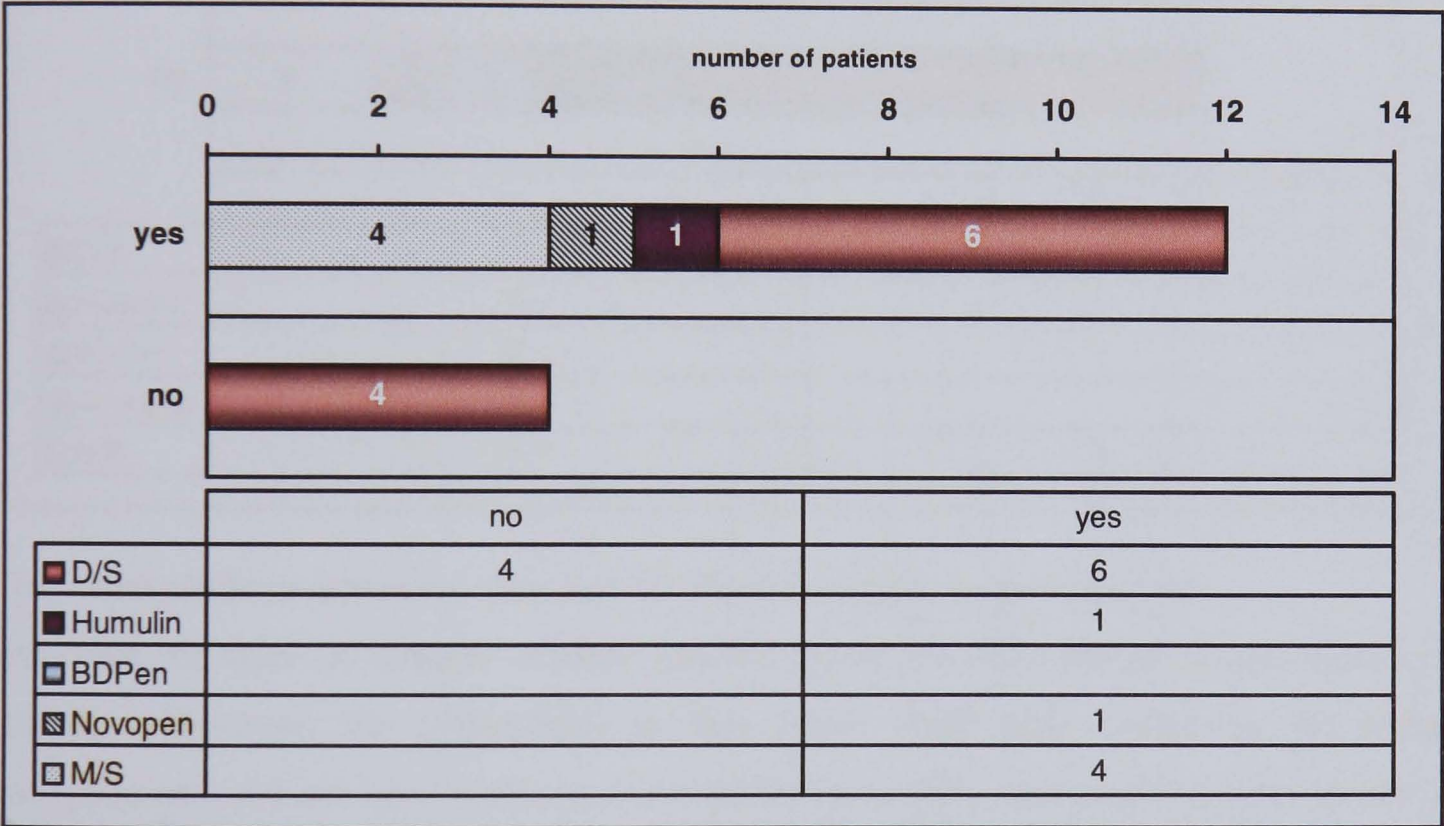
Q9. Is equipment always available when you need it?
Q10. If not always available, would you have preferred to buy it yourself?

Options were given for the respondent to tick 'yes' or 'no' and then, if 'yes' to Q9, they were asked to tick 'yes' or 'no' for Q10.

Q9

Yes	No
30	0

Q10



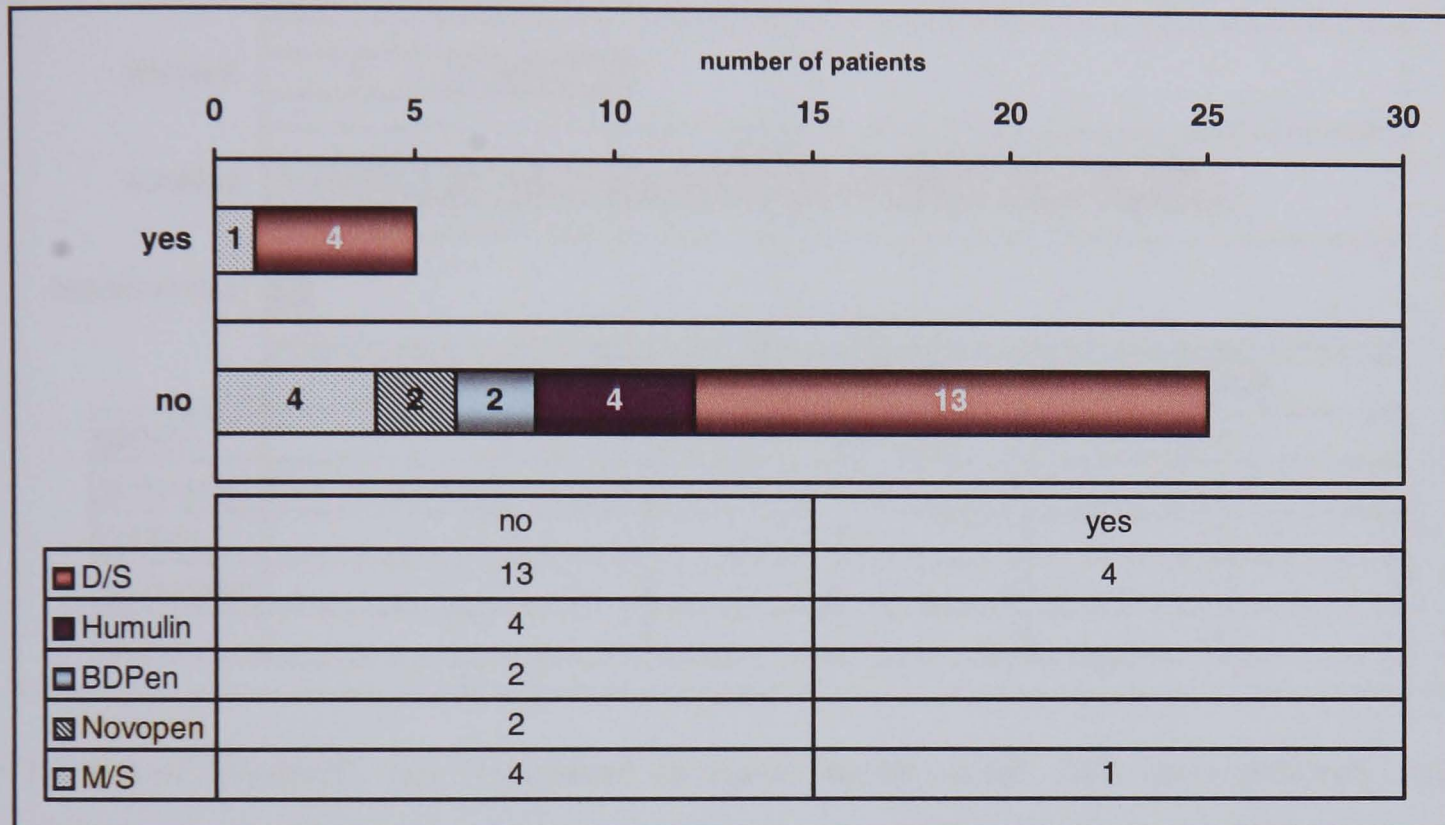
All respondents ticked 'yes' to Q9. 16 respondents provided 16 ticks to Q 10. Among the 16 ticks, 75% of ticks were 'yes', 25% of ticks were 'no'. 14 respondents (D/S: 7, Humulin: 3, BD Pen: 2, Novopen: 1 and M/S: 1) did not answer.

Q11. Do you know of any different (or better) equipment?

Q12. If yes to 11. Please give product names & types.

Q13. If yes to 11. What do you consider is better about this equipment in comparison with what you are currently using?

Options were given for the respondents to tick 'yes' or 'no' and then, if 'yes' to Q11, they were asked to give name and types of equipment and then answer to Q13.



16.7% of respondents answered 'yes' and 83.3% of respondents answered 'no'.

Many other pen types of syringes or blood glucose meters are available and information is also available. However, the respondents to this survey used their equipment on doctor's prescription and did not have access to information other than that obtained from nurses and other patients.

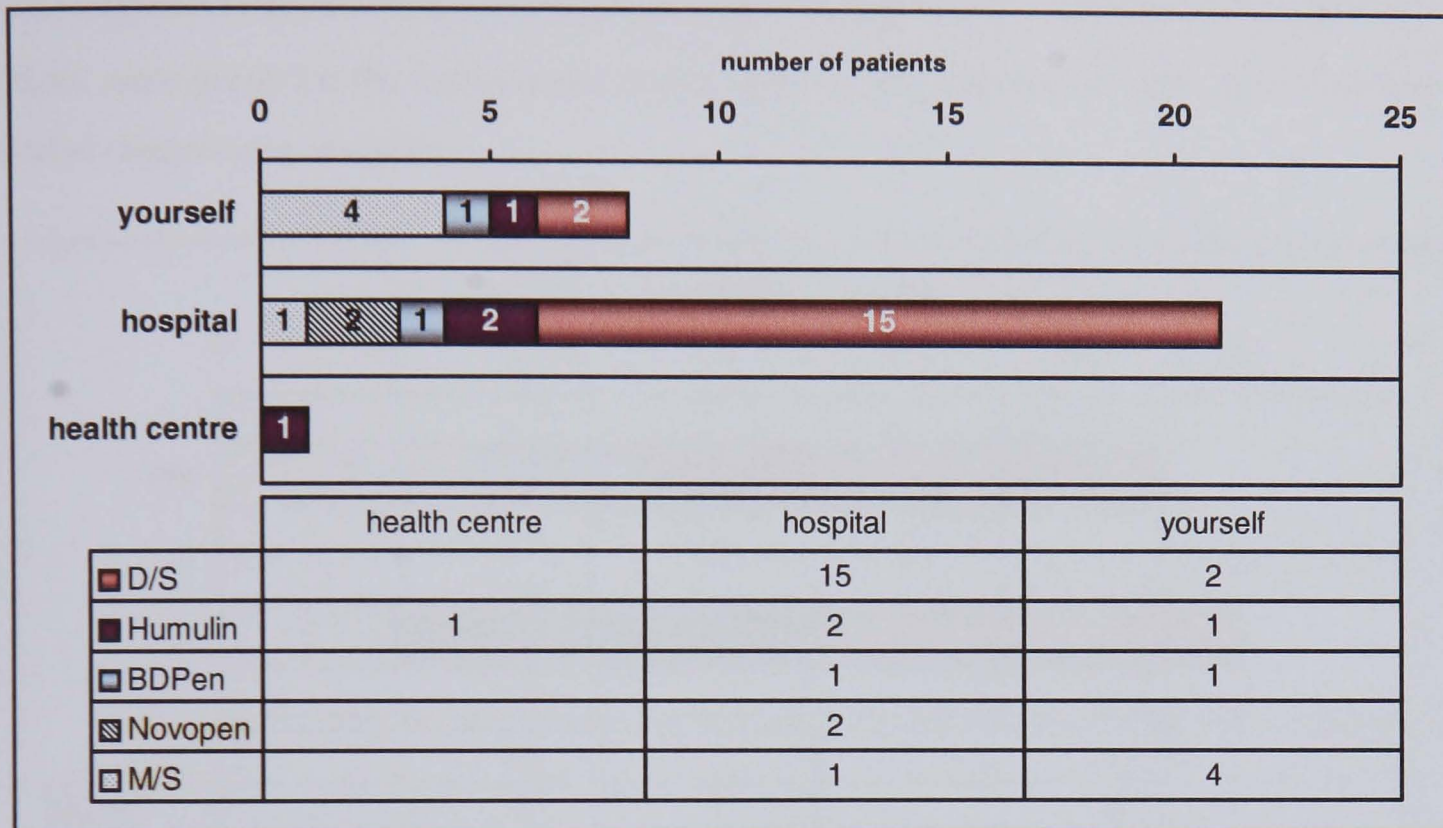
The following table gives product names & types and the reasons.

Current use	Different equipment	Comments
D/S user: 2	Pen type	
D/S user: 2	Micro Fine	Efficacious, easier to use, quicker
M/S user: 1	Quicker testing machine	Quicker

Q8. Who purchased the equipment?

The following options were available to tick appropriate answer: -

- yourself
- hospital
- others



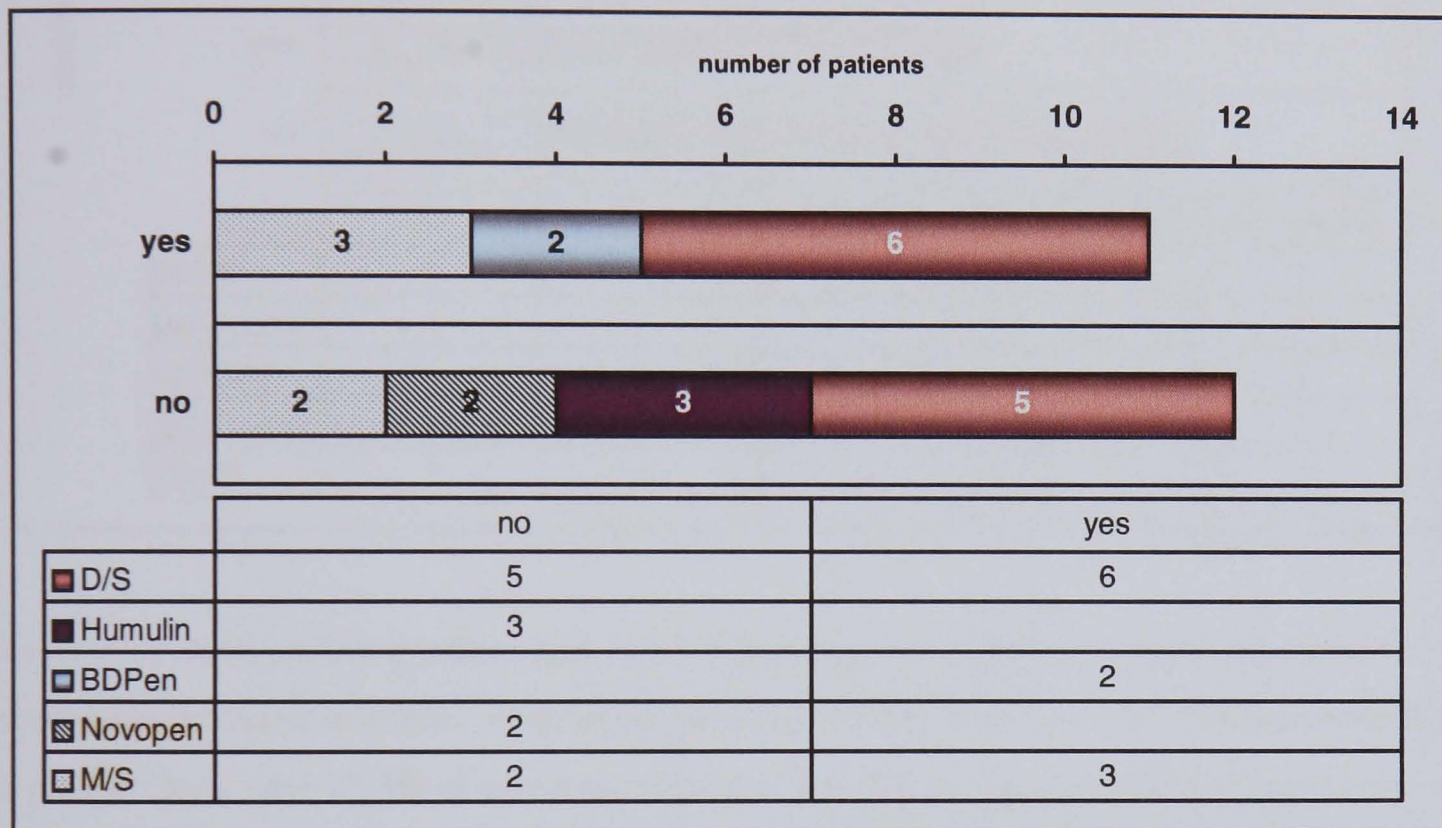
26.7% ticked 'yourself', one respondent answered health centre, 70% of respondents ticked hospital.

Objective 6. To identify opinions about any possible improvements.

Q17. Do you think there is scope for more home-care treatments with suitable equipment and back up?

Q18. If yes to 17. Can you suggest any examples?

Options were given for the respondents to tick 'yes' or 'no' and then if 'yes' to Q17 they were asked to suggest any examples.



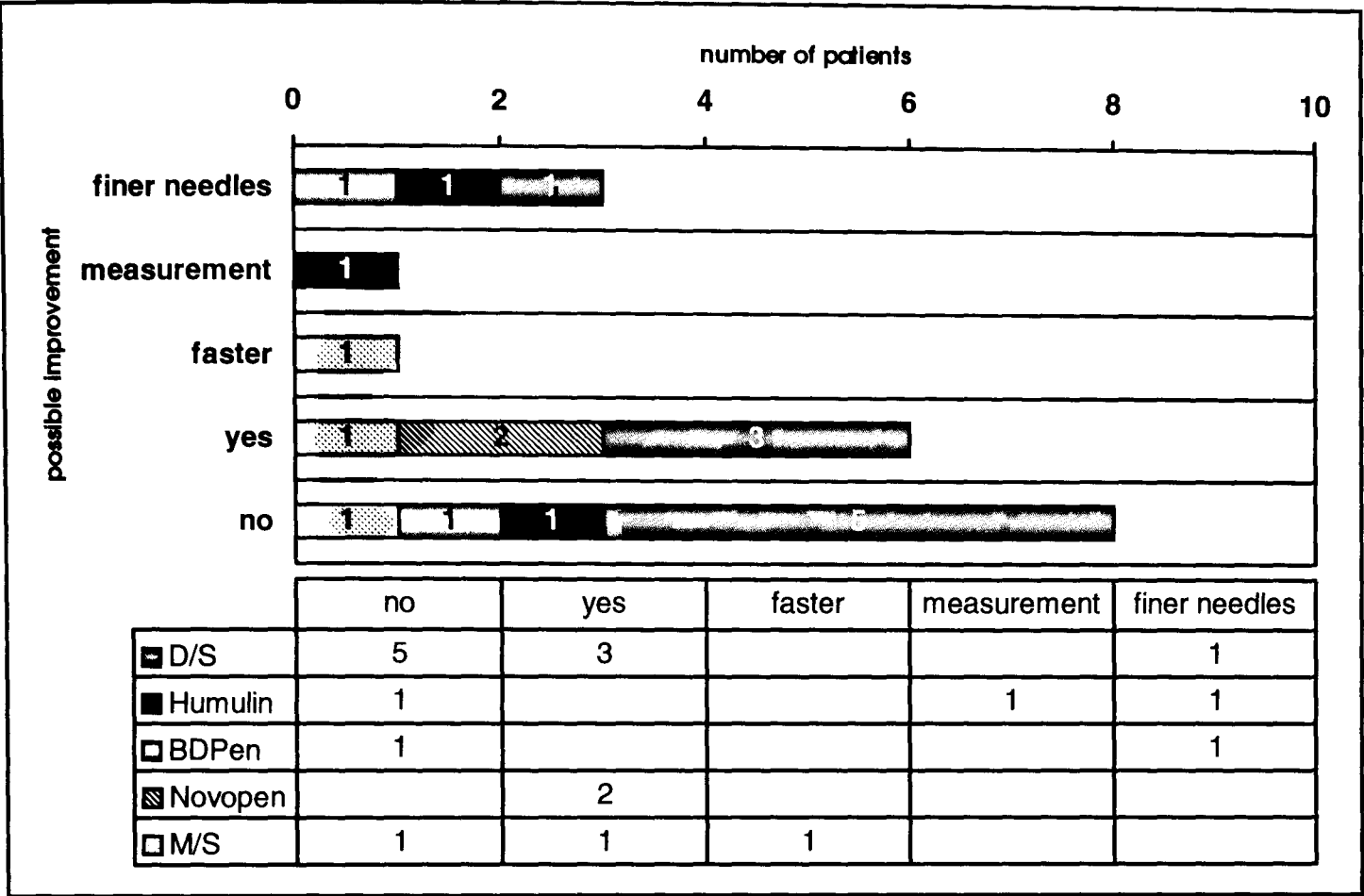
Respondents	Examples
D/S : 1	Machine to measure blood/ sugar level
D/S : 1	New technology
M/S :1	Availability to buy monitor as equipment from clinic
M/S : 1	Blood pressure measuring equipment/ Kenton measuring equipment
D/S: 5, BDPen: 1, M/S: 1	Unanswered

23 respondents provided 23 ticks. 47.8% of ticks were 'yes', 52.1% of ticks were 'no'.

7 respondents (D/S: 6 and Humulin: 1) did not answer. The above table suggests that suitable equipment can be designed within their treatment area and also other possible areas.

Q21. Could your equipment be improved & how?

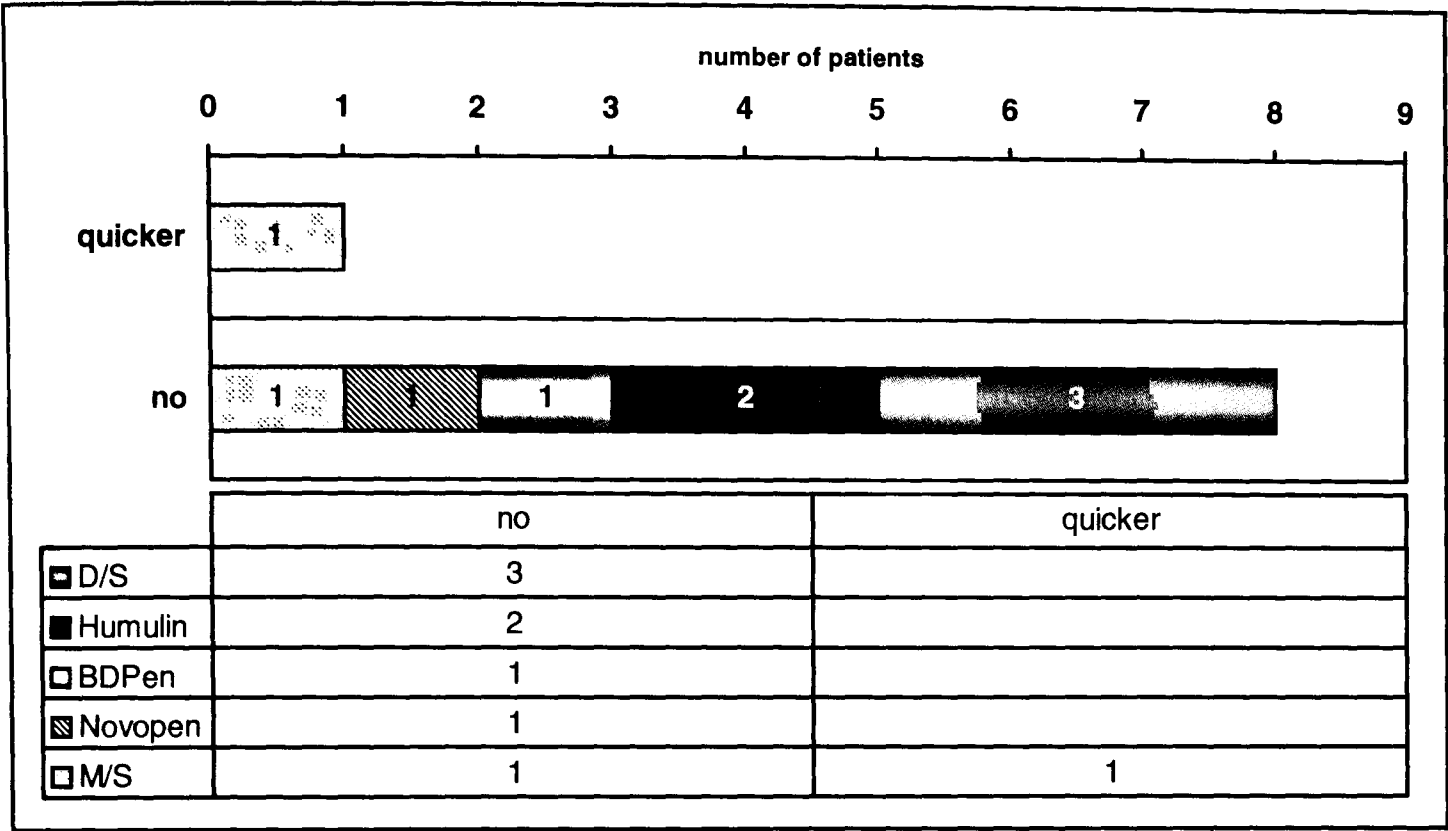
No options were given.



This was an open-ended question and content analysis was used to explore the answers. 19 respondents provided answers. Among the answers, 31.6% were ‘yes’ but the respondents did not answer ‘how’ and 15.8% of answers referred to making needles even finer. One answer was the syringe could do with having the measurements highlighted in the same way as each unit. One answer was to be even faster and more discrete for testing in public and 42.1% of answers were ‘no’. 11 respondents (D/S: 8, Humulin: 1 and M/S: 2) did not answer.

Q22. Is there anything more you would like to say about the equipment you use?

No options were given.



This was an open-ended question and only one of the respondents using the monitoring system answered that the test could be quicker. 8 respondents answered 'no' and 21 respondents (D/S: 14, Humulin: 2, BD Pen: 1, Novopen: 1 and M/S: 2) did not answer.

4.6 Nebuliser user survey

This section provides the analysis of a questionnaire survey at the Respiratory Unit of Leicester Glenfield Hospital. The questionnaires were filled in by 30 respondents in the presence of the researcher.

4.6.1 Description of equipment

Many types of medication are available as inhaled treatments. The study identified that nebulisers are used in this Respiratory Unit for home care (National Jewish Medical and Research Center, 1994).

Inhaled methods deliver medication directly to the airway, which is particularly useful for respiratory problems. A nebuliser is a device which turns a liquid into a mist. Nebuliser therapy is usually given to patients who have obstructed or narrowed airways. The drug given is designed to relax and open up the muscle in the airways and make breathing much easier (Vara, 1996). For the Respiratory Unit survey, respiratory system, asthma and nebuliser were studied to become more familiar with the subject area.

4.6.1.1 Respiratory system

The respiratory system, including the lungs, brings air into the body. The oxygen in the air travels from the lungs through the bloodstream to cells in all parts of the body. The cells use the oxygen as fuel and give off carbon dioxide as a waste gas. The waste gas is carried by the bloodstream back to the lungs to be eliminated or exhaled. The lungs accomplish this vital process - called gas exchange - using an automatic and quickly adjusting control system (Coates, et al., 1997).

In addition to gas exchange, the lungs and the other parts of the respiratory system have important jobs to do related to breathing. These include:

- Bringing all air to the proper body temperature
- Moisturising the inhaled air for necessary humidity
- Protecting the body from harmful substances by sneezing, filtering or swallowing them, or by alerting the body through the sense of smell

- Defending the lungs with:
 1. cilia - microscopic hairs along the air passages
 2. phlegm (mucus or sputum) - a moving carpet of phlegm collects dirt and germs inhaled into the lungs and moves them out to be coughed up or swallowed
 3. macrophages - scavenger cells in the lungs that literally eat up dirt and germs invading the lungs(Asthma & Lung Specialists, 1995).

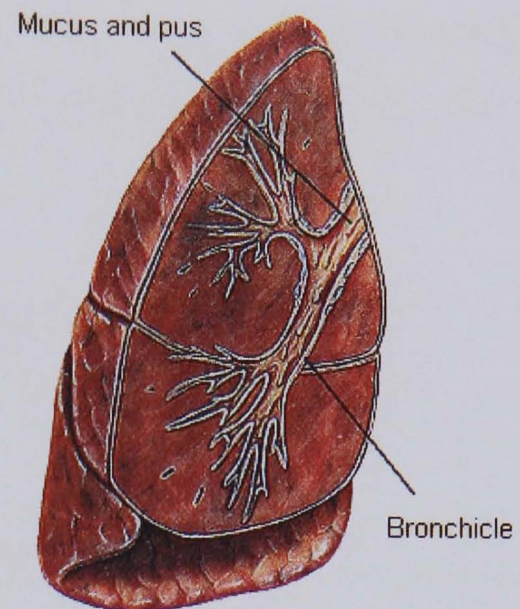


Figure 4-22. Bronchiole (Source: Asthma & Lung Specialists, 1995)

Asthma is a disease that affects the lungs and the airways that deliver air to the lungs. It causes periodic attacks of wheezing and difficult breathing. An asthma attack occurs when the airways become inflamed in response to a trigger, such as dust, mould, pets, exercise, or cold weather. However, some attacks start for no apparent reason. Triggers may inflame the airways to the lungs, allowing disease-fighting cells to accumulate and causing swelling in the lungs. In addition, the airways may become blocked or obstructed when the muscles surrounding the lungs tighten or go into spasm. This keeps air from circulating freely in the lungs. Or, mucus may clog and narrow the airways in the lungs, making breathing even more difficult. (The Foundation for Better Health Care, 1997)

4.6.1.2 What is a nebuliser?

A nebuliser is a device used to administer asthma medication. The nebuliser is powered by a compressor that allows asthma medication to be taken in the form of a mist (wet aerosol). A nebuliser delivery system consists of a nebuliser (a small plastic bowl with a screw-top lid) and a source for compressed air. The air flow to the nebuliser changes the medication solution to a mist. When inhaled correctly, the medication has a better chance to reach the small airways. This increases the medication's effectiveness (National Asthma Education Program Office of Prevention, 1992).

There are three parts to a nebuliser: a cup; a mouthpiece or mask attached to a 'T' shaped part; and thin, plastic tubing that connects to the compressor. A nebuliser helps ensure that patients get the right amount of medication. Four types of patients can be identified as follows:

- Children under the age of 5 years
- Patients who have difficulty using metered-dose inhalers
- Patients with severe asthma
- Patients with acute asthma attacks

(National Asthma Education Program Office of Prevention, 1992)

4.6.1.3 Equipment for nebuliser therapy

Medix AC2000 Hi Flo

This model is designed for home use. It delivers a high flow rate for nebulisation of respiratory drugs including bronchodilators, antibiotics and steroids. Most particles are below 5microns and typical air flow 8 litres per minute (Westons, 1997).



Figure 4-23. Medix AC 2000 Hi Flo



Figure 4-24. Medix World Traveller

Medix World Traveller

This model is designed for travelling. It includes all the features of the AC2000 Hi Flo, plus it automatically adjusts to mains voltage for the mobile user. An optional battery pack is also available, so it can be used in a car with a 12V DC supplied via a car cigar lighter lead (Westons, 1997).

Medix Econoneb

This model is designed for home, clinic and ward use. It has a top carrying handle, when continuous use may be required. It delivers a high flow rate for fast nebulisation of all respiratory drugs (Westons, 1997).



Figure 4-25. Medix Econoneb

Medix Sonix 2000



Figure 4-26. Medix Sonix 2000

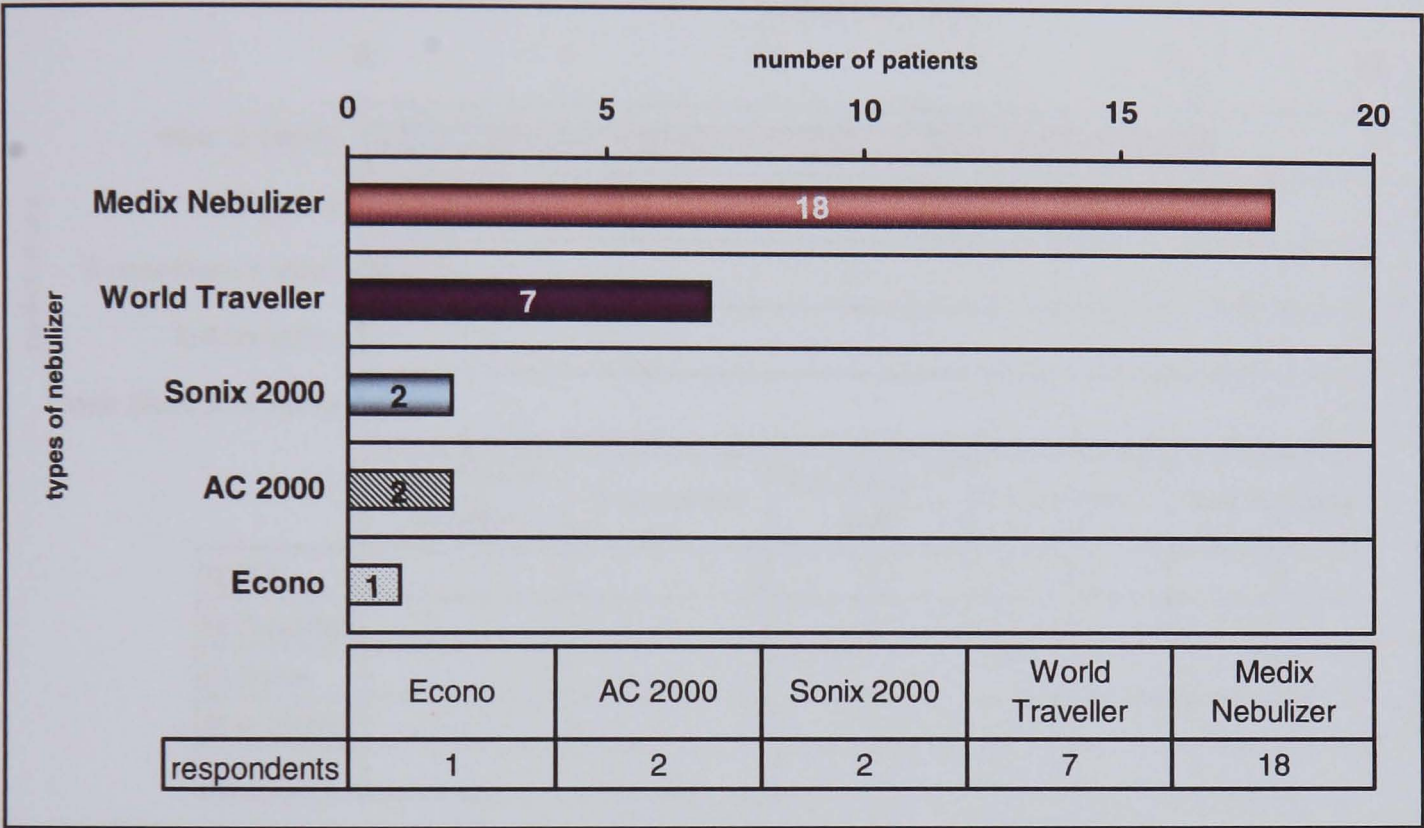
This model is compact and operation is from a handheld ultrasound unit which can be used for bronchodilators and antibiotics. It features variable flow rate, mouthpiece and cover. At the end of treatment, the handset bleeps and automatically stops nebulising and displays a red light, and automatically adjusts to mains voltage. An optional battery pack is available as well as a 240V plug-in wall transformer as an alternative to multi-volt power supply unit. 220V and 115V versions of plug-in wall transformers are also available (Westons, 1997).

4.6.2 Results of the nebuliser user questionnaire survey

Objective 1. To identify treatment & equipment types used.

Q1. What types of medical equipment / health-care equipment are you using?

The total number of respondents were thirty patients who were all using different types of nebuliser. The number of patients and the types of equipment used are illustrated in the table below;



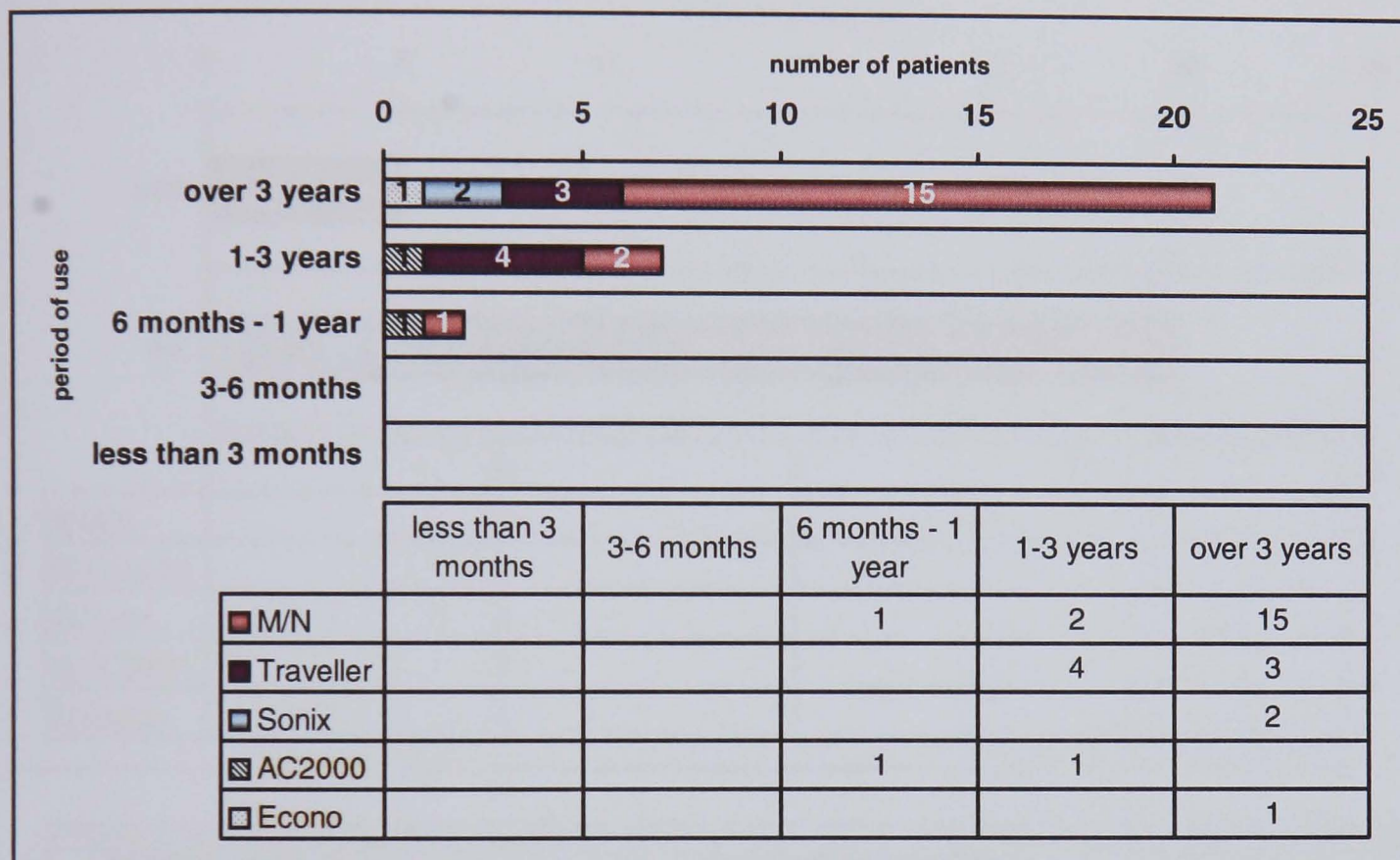
Hospital	Types of nebuliser & patients
Leicester Glenfield Hospital Respiratory Physiology Unit	M/N: 18 Traveller: 7, Sonix.: 2, AC2000: 2, Econo.: 1

60% of respondents used the Medix Nebuliser, 23.3% of respondents used the Medix World Traveller, two respondents used the Medix Sonix 2000, two respondents used the Medix AC 2000 and one respondent used the Medix Econo.

Q2. How long have you been using this equipment?

The following options were available to tick appropriate answer: -

- less than 3 months
- 3-6 months
- 6 months - 1 year
- 1-3 years
- over 3 years

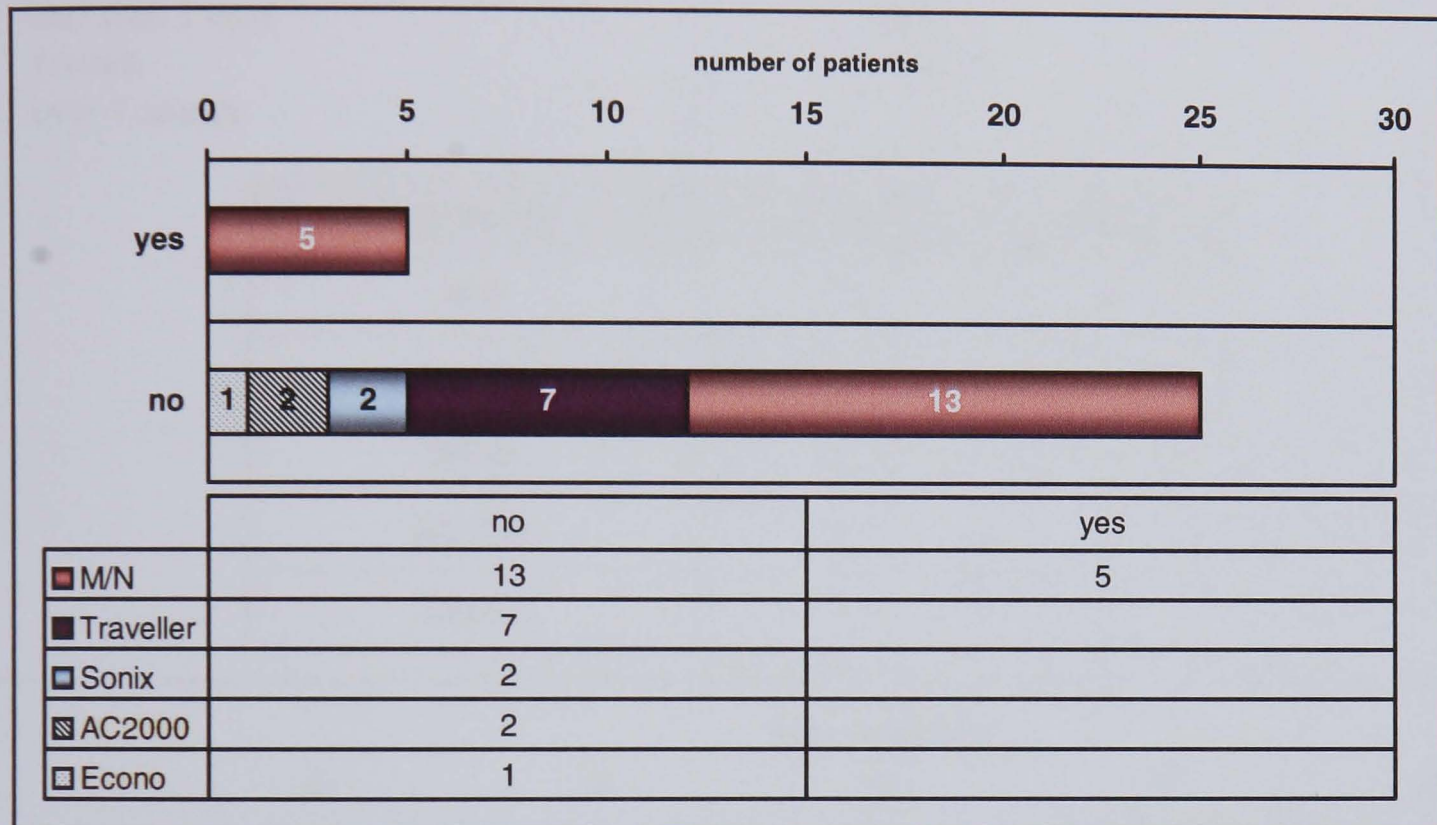


70% of respondents had used their equipment for over 3 years and 23.3% of respondents for 1-3 years and only two respondents had been using the equipment for 6 months to 1 year. Therefore the majority of users were quite experienced patients.

Q15. Do you have any other hospital equipment and home use equipment, related to the same treatment?

Q16. If yes to 15. Please give equipment names & types

The options that were given to the respondents were to tick 'yes' or 'no' and then if 'yes' to Q15 they were asked to give the name of the equipment and its use.



Respondents	Product names & types
M/N: 3	Oxygen
M/N: 1	Volumatic
M/N: 1	Flow meter

Only five respondents (16.6%) answered 'yes' and most respondents (83.3%) answered 'no'.

Objective 2. To identify the nature of equipment user training.

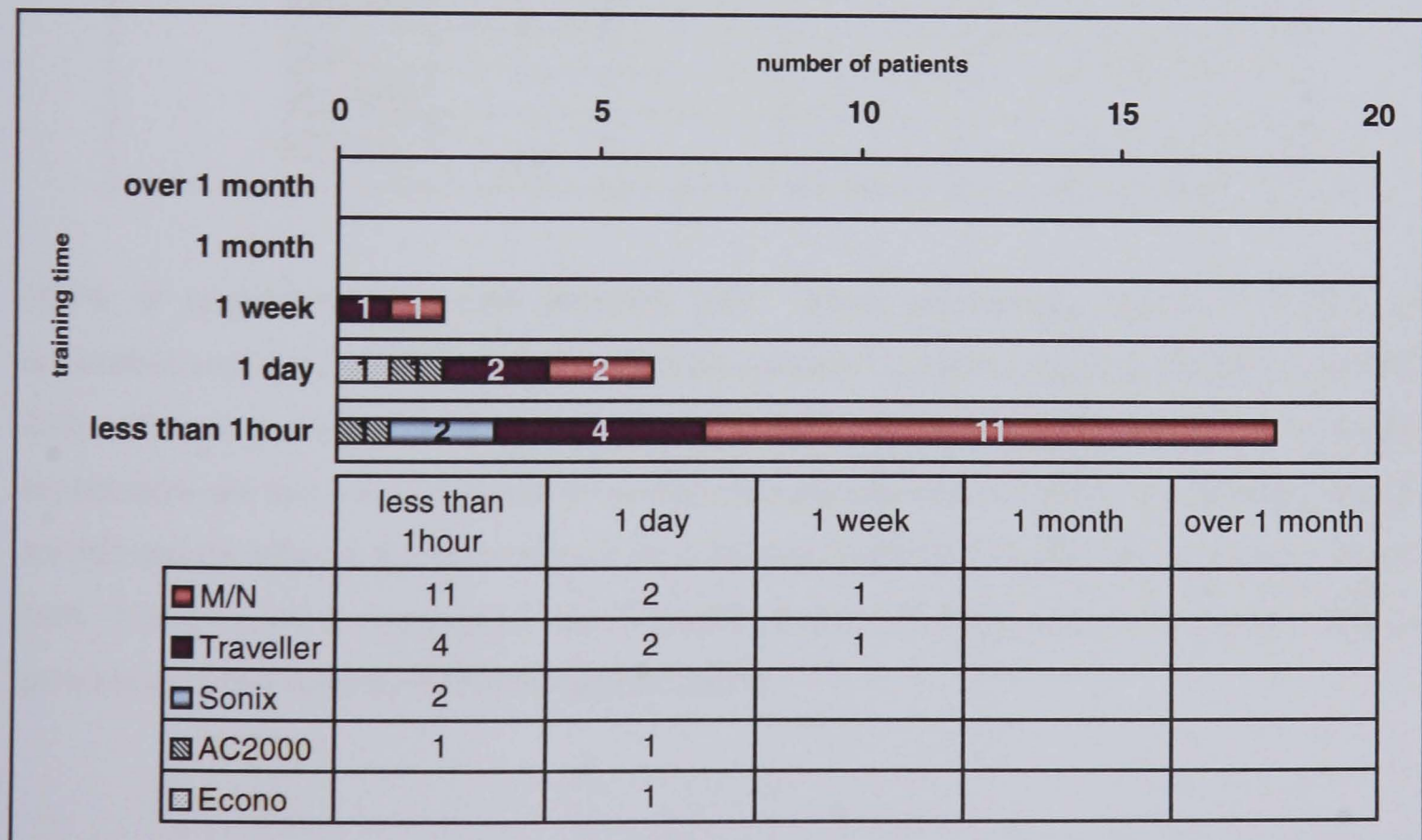
Q3. Have you ever received training before using this equipment?

Q4. If yes to 3. How long were you trained?

The options that were given for the respondent were to tick 'yes' or 'no' and then if 'yes' to Q3 they were asked for the training time. The following options were available for ticking: -

- less than 1 hour
- 1 week
- over 1 month
- 1 day
- 1 month

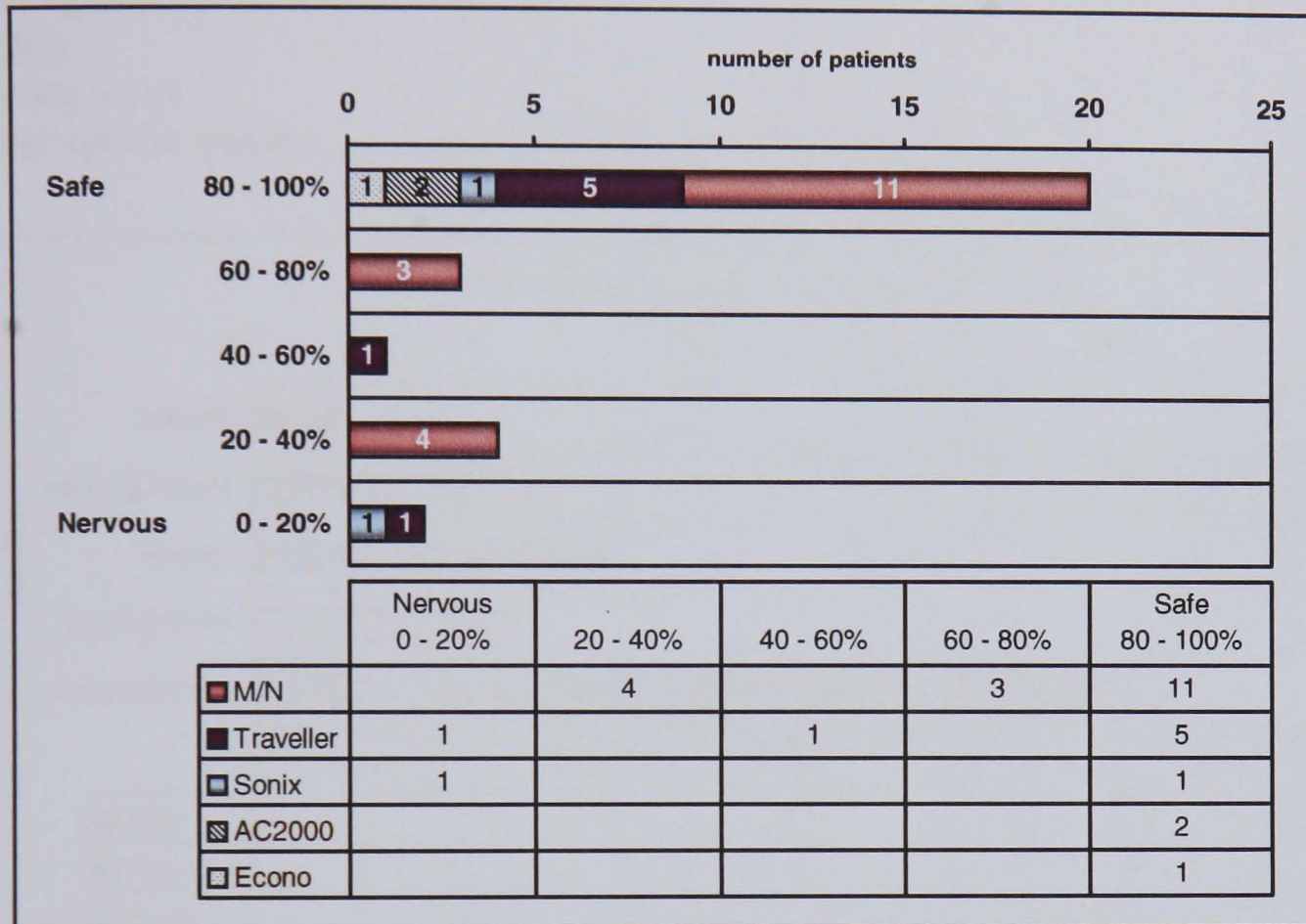
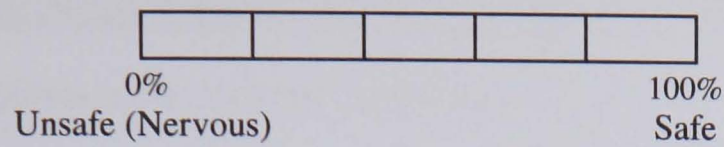
Equipment	Yes	No
M/N	14	4
Traveller	7	
Sonix	2	
AC 2000	2	
Econo	1	



26 patients had been trained before using the equipment. Among them, two respondents had been trained for 1 week, 23% of respondents had received training for 1 day and 69.2% of respondents had received training for less than 1 hour. Therefore vast majority of users (92.2%) had received training before home use of less than an hour.

Q5. When you first used this equipment, how did you feel about it?

The following five point scale options were available for ticking: -



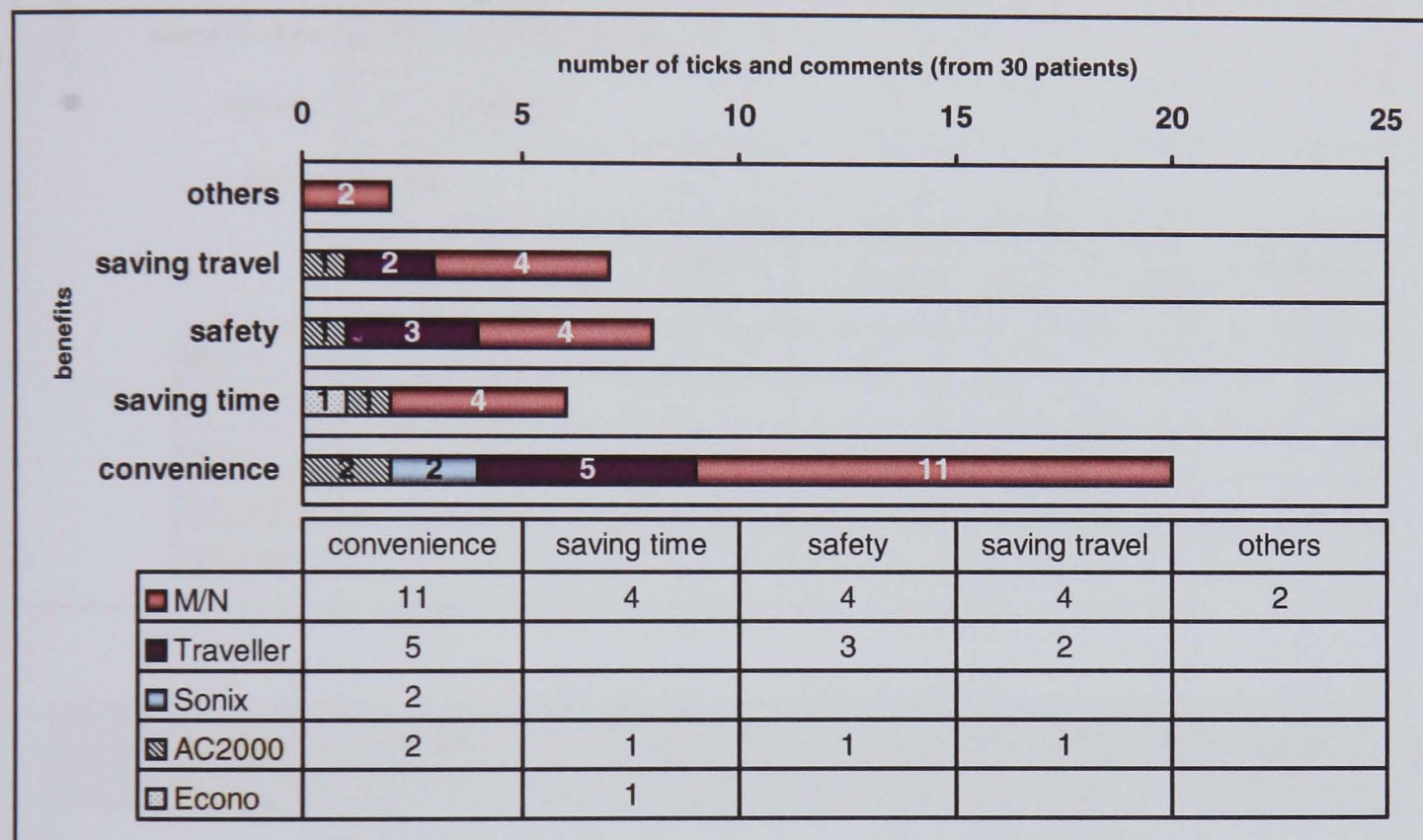
66.7% of respondents answered 80-100% safe. Three respondents answered 60-80%, one respondent answered 40-60%, four respondents answered 20-40%, two respondents answered 0-20%. This is a similar result to the haemo dialysis equipment user survey. Two possible explanations are that a longer period of training and experience gave them a psychologically safer attitude and the other is that they might have forgotten how they felt when the equipment was first used. However, the 2 respondents with 6 months' to 1 year's experience of using the equipment gave answers that were no different from the others.

Objective 3. To identify opinions about benefits of use.

Q14. What are the benefits of using this product at home?

The following options were available for ticking.

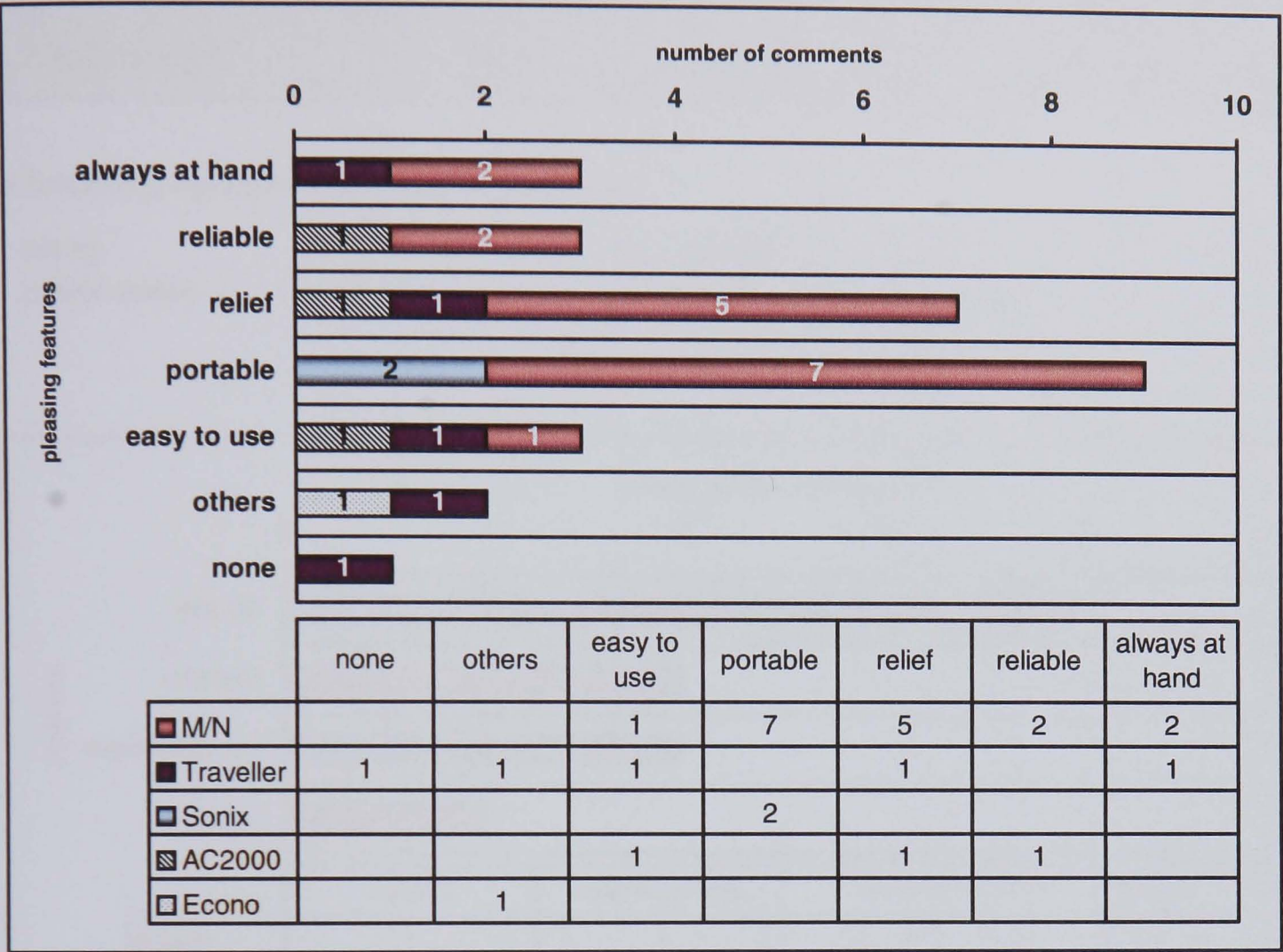
- convenience
- saving time
- safety
- saving travel
- other (please specify) _____.



30 patients provided 43 ticks and other comments. 46.5% of ticks were for convenience, 14% of ticks were for saving time, 18.6% of ticks were for safety and 16.3% of ticks were for saving travel. One respondent answered 'do not have to go into hospital as often' and one respondent answered 'it helps to remove sterol congestion'.

Q20. What is the most pleasing feature of your equipment?

No options were given.



Respondents	Other pleasing feature & comments
Traveller: 1	240 Volt
Econo: 1	Lack of admissions

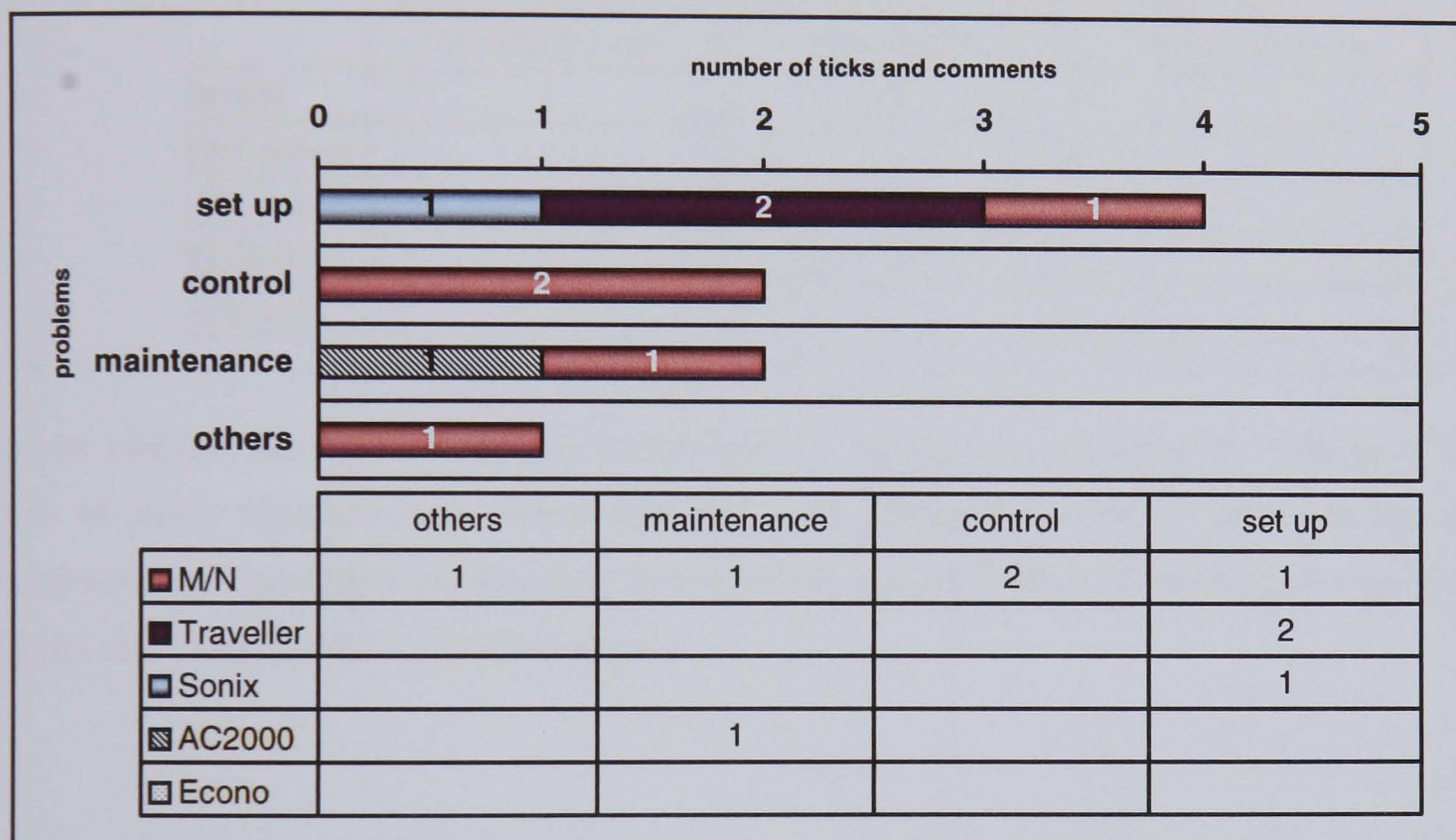
This was an open-ended question with varieties of answers and content analysis was used to explore the answers. 23 respondents answered, among whom, 13% referred to always at hand, 13% mentioned reliable, 30.4% referred to relief, 39.1% to portable, 13% referred to ease of use. Two respondents gave other answers as above. One respondent answered none. 7 respondents (M/N: 5 and Traveller: 2) did not answer.

Objective 4. To identify opinions about problems of use.

Q6. When you first used this equipment, did you have problems with any of the following?

The following options were available for ticking: -

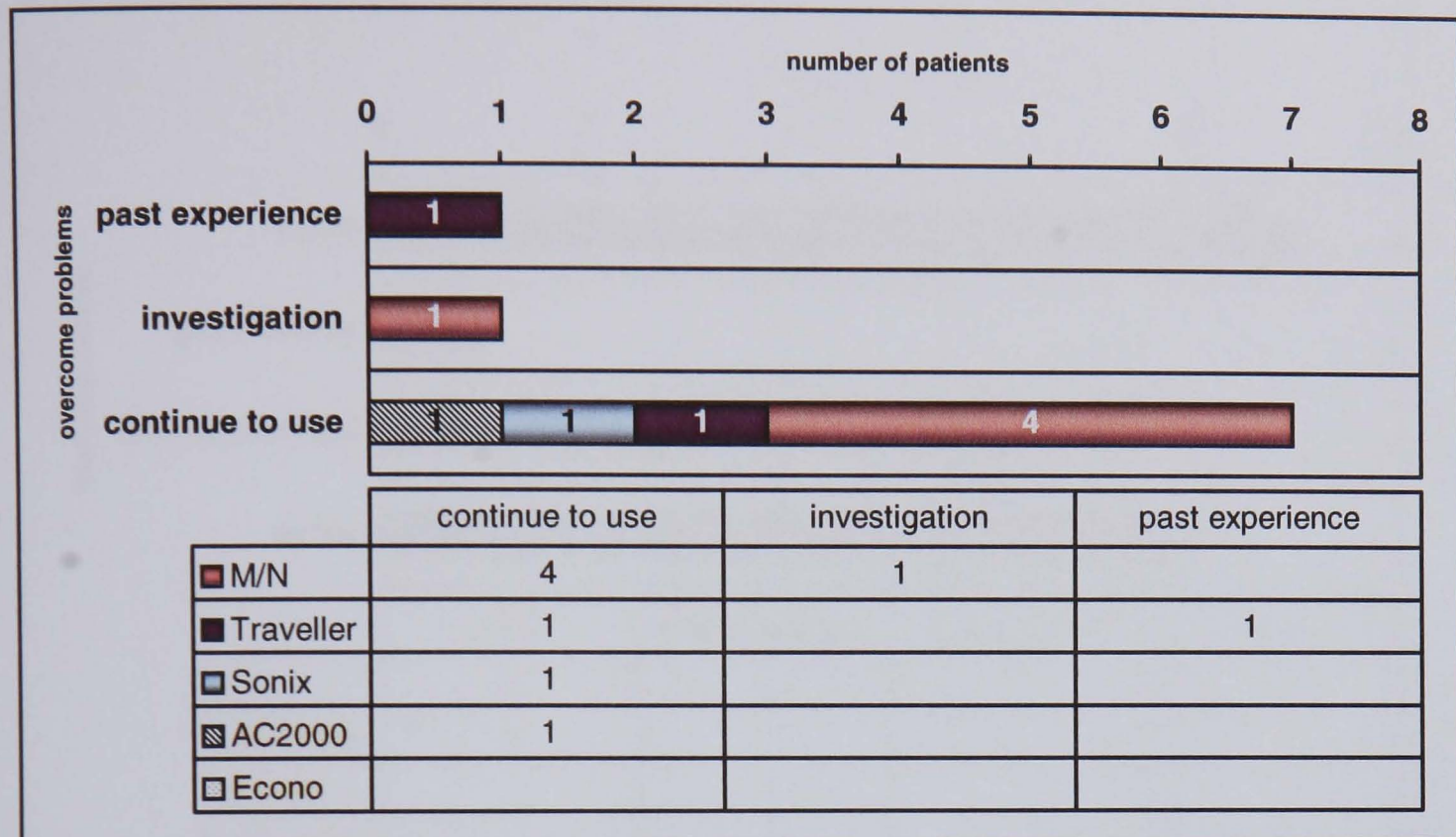
- set up
- maintenance
- control
- or others (please specify)



9 respondents answered. Four respondents ticked set up, two respondents ticked control, two respondents ticked maintenance, one respondent answered 'other' such as finding out about services and replacement parts e.g. mask, drive line. 21 respondents (M/N: 13, Traveller: 5, Sonix: 1, AC2000: 1 and Econo: 1) answered 'no problems'.

Q7. How did you overcome these problems?

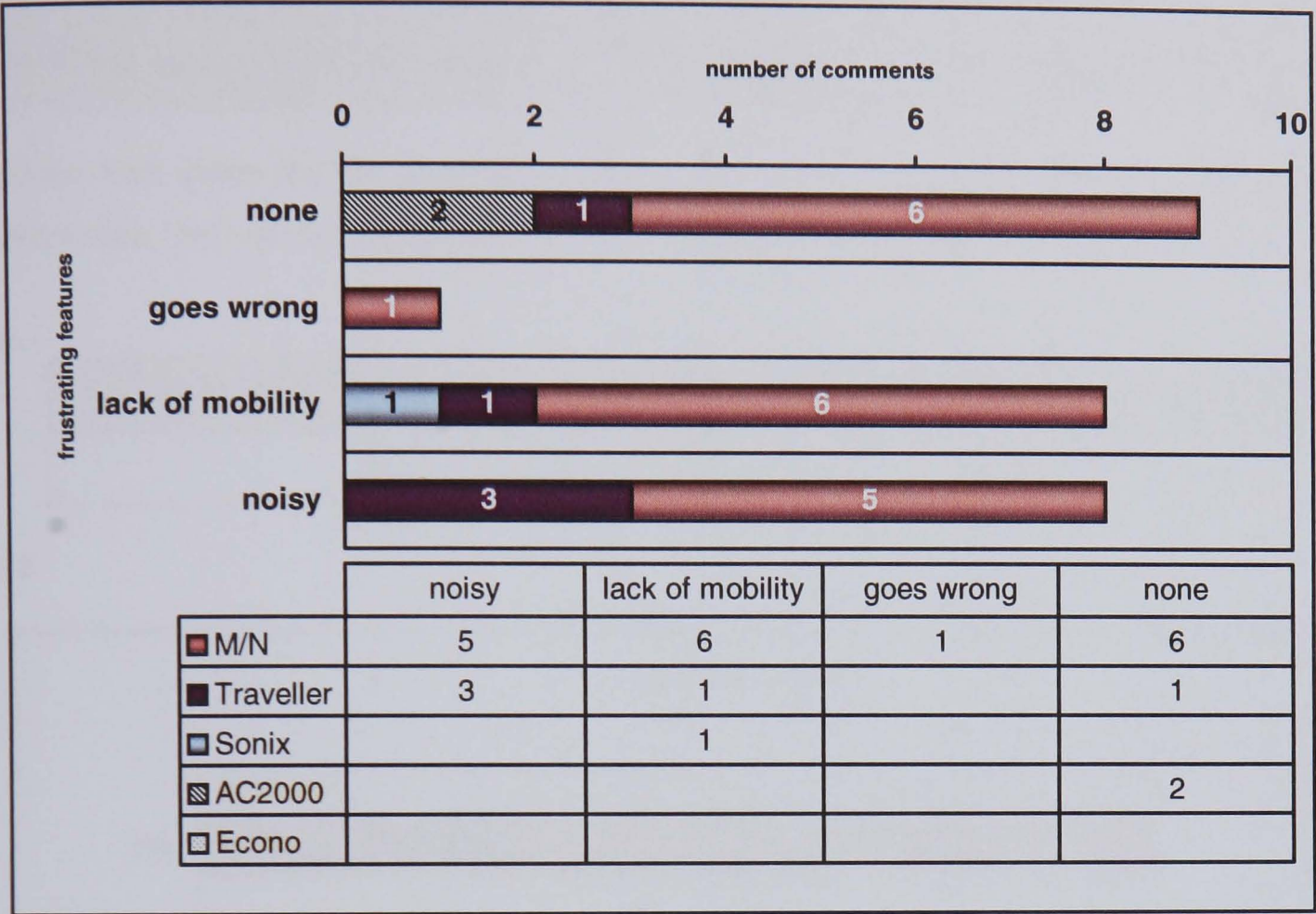
No options were given.



Content analysis was used to explore the answers. 9 respondents answered in addition to Q6, seven of these respondents answered that they had continued to use it, with practice and experience, one respondent answered by investigation, one respondent answered past experience and two respondents (M/N: 2) did not answer.

Q19. What is the most frustrating and annoying feature of your equipment?

No options were given.



This was an open-ended question and content analysis was used to explore the answers. 24 respondents provided 26 answers. Among the 26 answers, 30.8% of answers related to 'noisy', 30.8% referred to 'lack of mobility', one answer was 'goes wrong', 34.6% of answers referred to 'none'. 6 respondents (M/N: 2, Traveller: 2, Sonix: 1 and Econo: 1) did not answer.

Objective 5. To identify opinions about availability/ loan/ ownership.

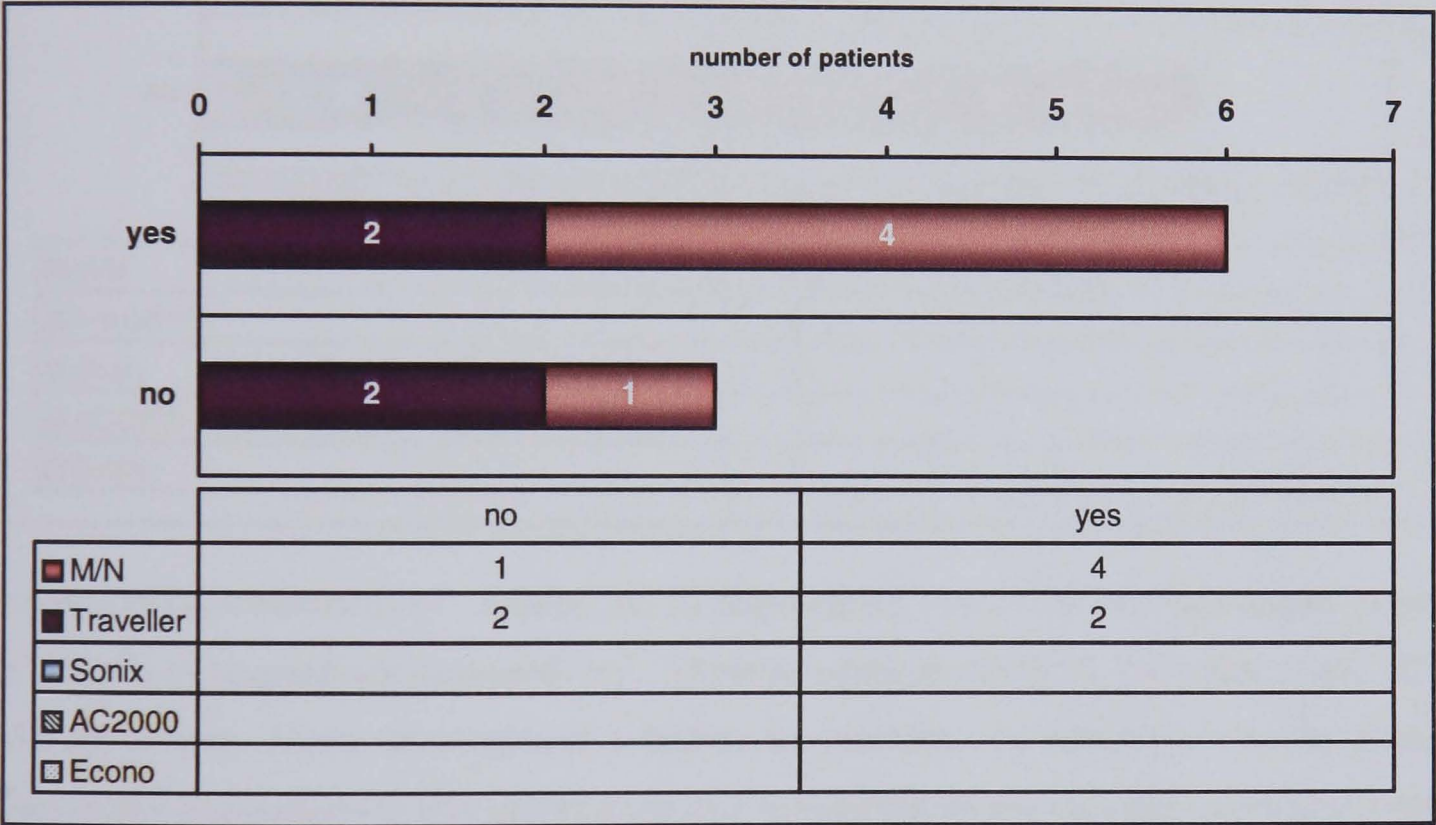
- Q9. Is equipment always available when you need it?
Q10. If not always available, would you have preferred to buy it yourself?

Options were given for the respondent to tick 'yes' or 'no' and then if 'yes' to Q9 they were asked to tick 'yes' or 'no' for Q10.

Q9

Yes	No
30	0

Q10



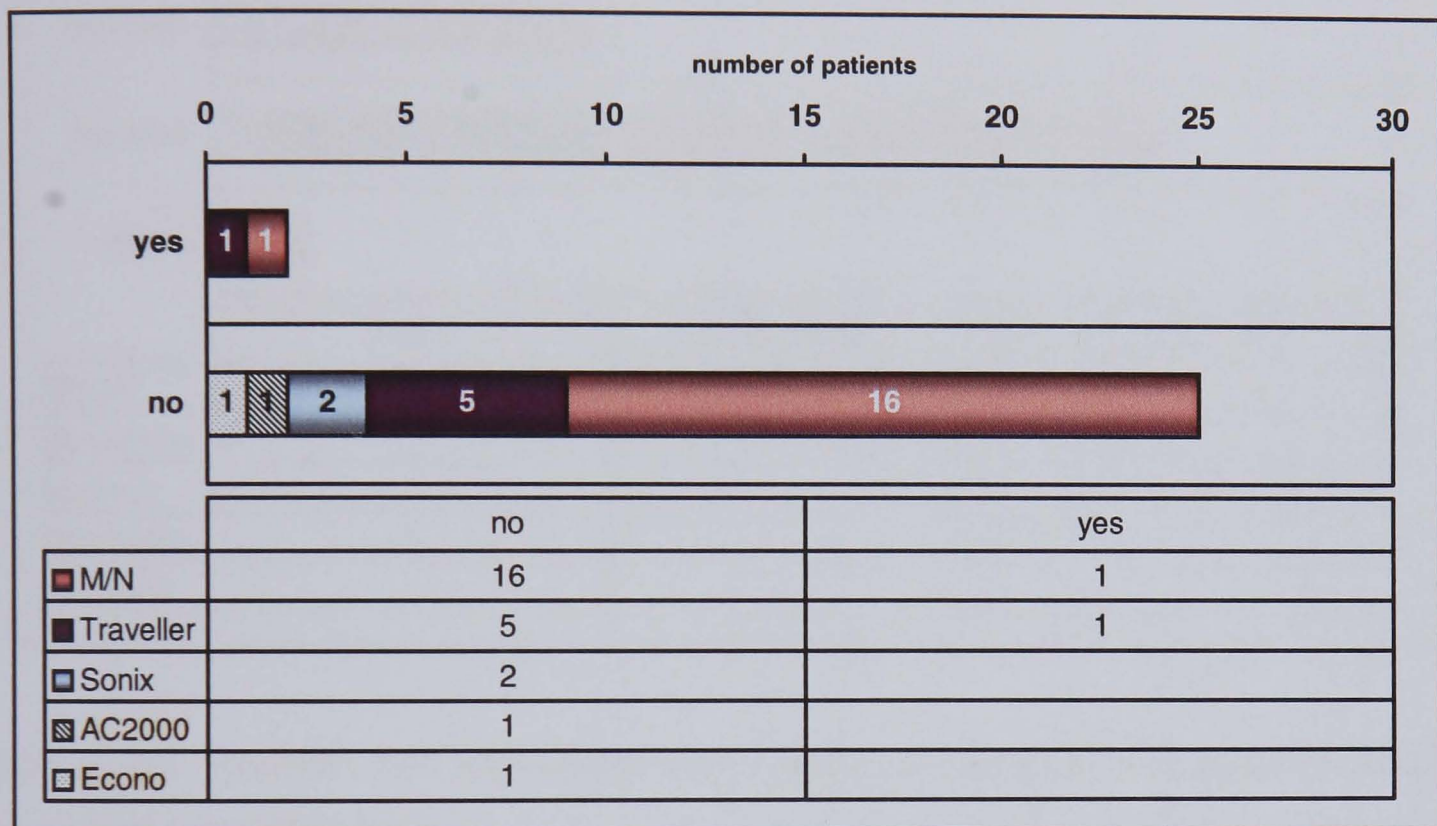
All respondents ticked 'yes' to the first question. For Q10 six respondents ticked 'yes', three respondents ticked 'no' and 21 respondents (M/N: 13, Traveller: 3, Sonix: 2, AC2000: 2 and Econo: 1) did not answer.

Q11. Do you know of any different (or better) equipment?

Q12. If yes to 11. Please give product names & types.

Q13. If yes to 11. What do you consider is better about this equipment in comparison with what you are currently using?

Options were given for the respondent to tick 'yes' or 'no' and then if 'yes' to Q11 they were asked to give name and types of equipment and then answer to Q13.



27 respondents answered Q 11. Among the 27 respondents, two (7.4%) of respondents answered 'yes', 92.6% of respondents answered 'no'. Three respondents (M/N: 1, Traveller: 1 and AC200: 1) did not answer. Many other types of nebuliser are available and information is also available. However, the respondents to this survey used their equipment on doctor's prescription and did not have access to information other than that obtained from nurses and other patients.

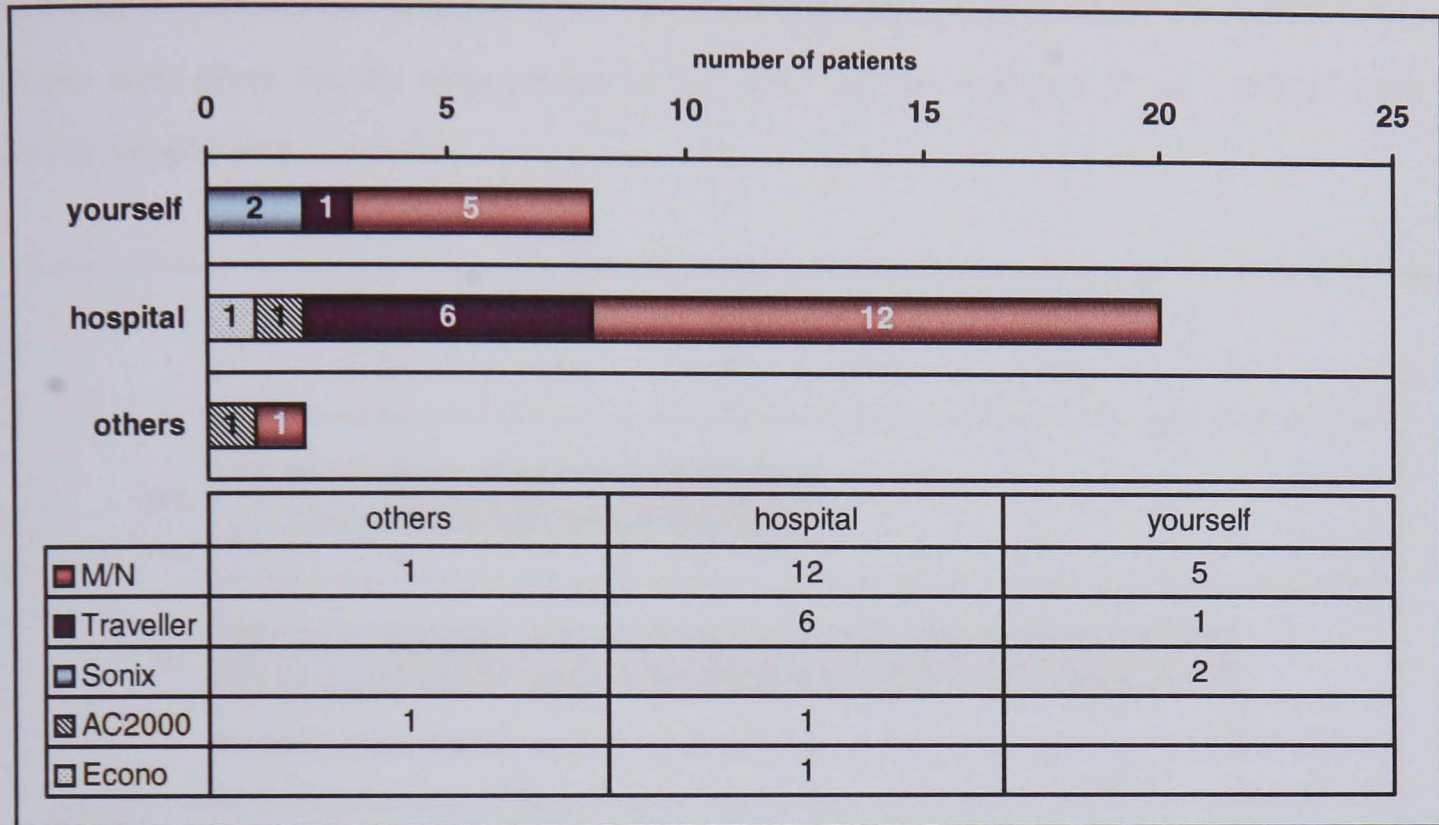
The following table gives product names & types and the reasons.

Current use	Different equipment	Comments
Traveller user; 1	Sonic 2000	
M/N user; 1	Smaller & lighter	Smaller & lighter

Q8. Who purchased the equipment?

The following options were available to tick an appropriate answer: -

- yourself
- hospital
- others



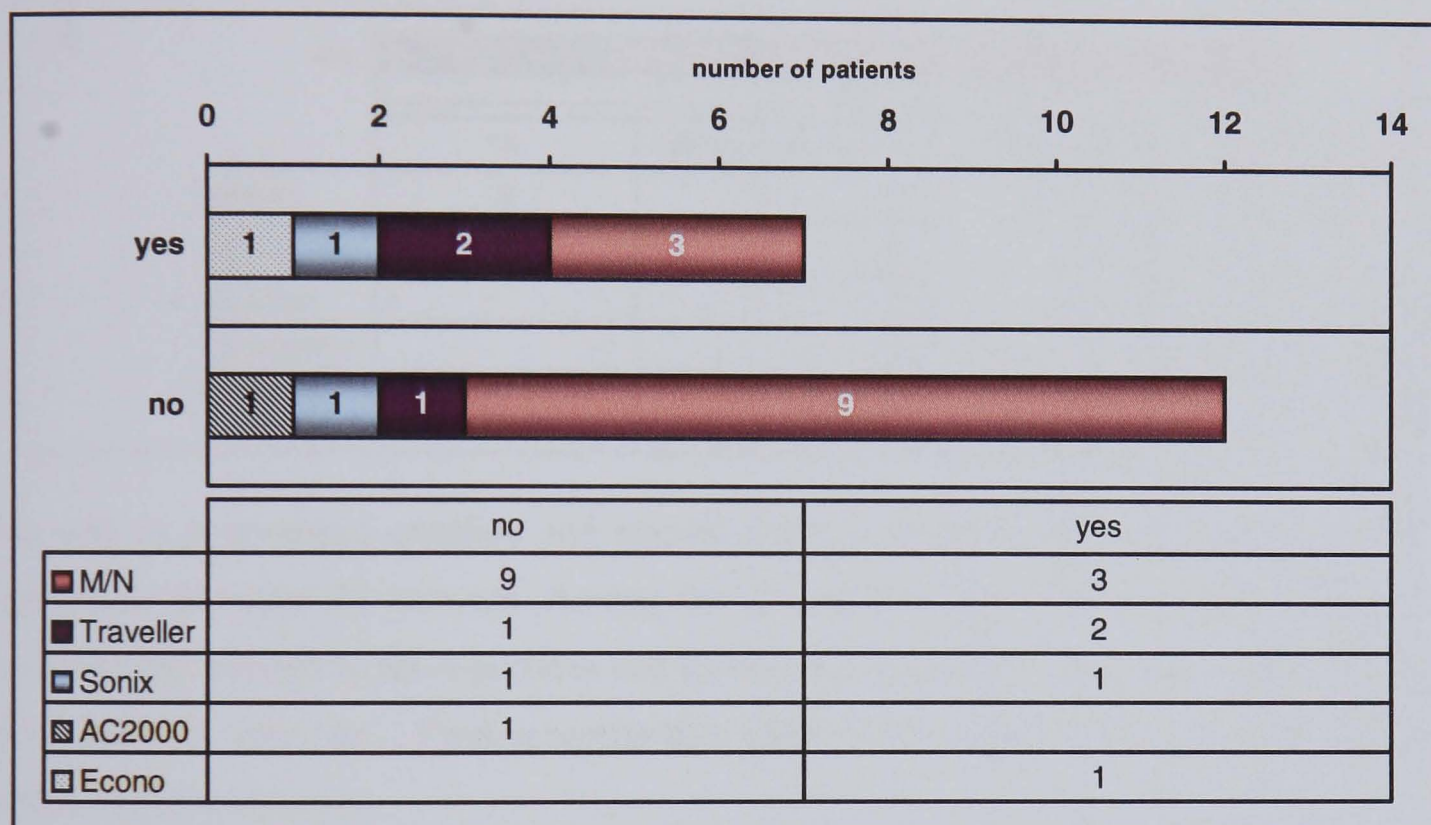
26.6% ticked 'yourself', two respondents (6.7%) answered 'the Red Cross and GP', 66.6% of respondents ticked 'hospital'.

Objective 6. To identify opinions about any possible improvements.

Q17. Do you think there is scope for more home-care treatments with suitable equipment and back up?

Q18. If yes to 17. Can you suggest any examples?

Options were given for the respondents to tick 'yes' or 'no' and then if 'yes' to Q17 they were asked to suggest any examples.



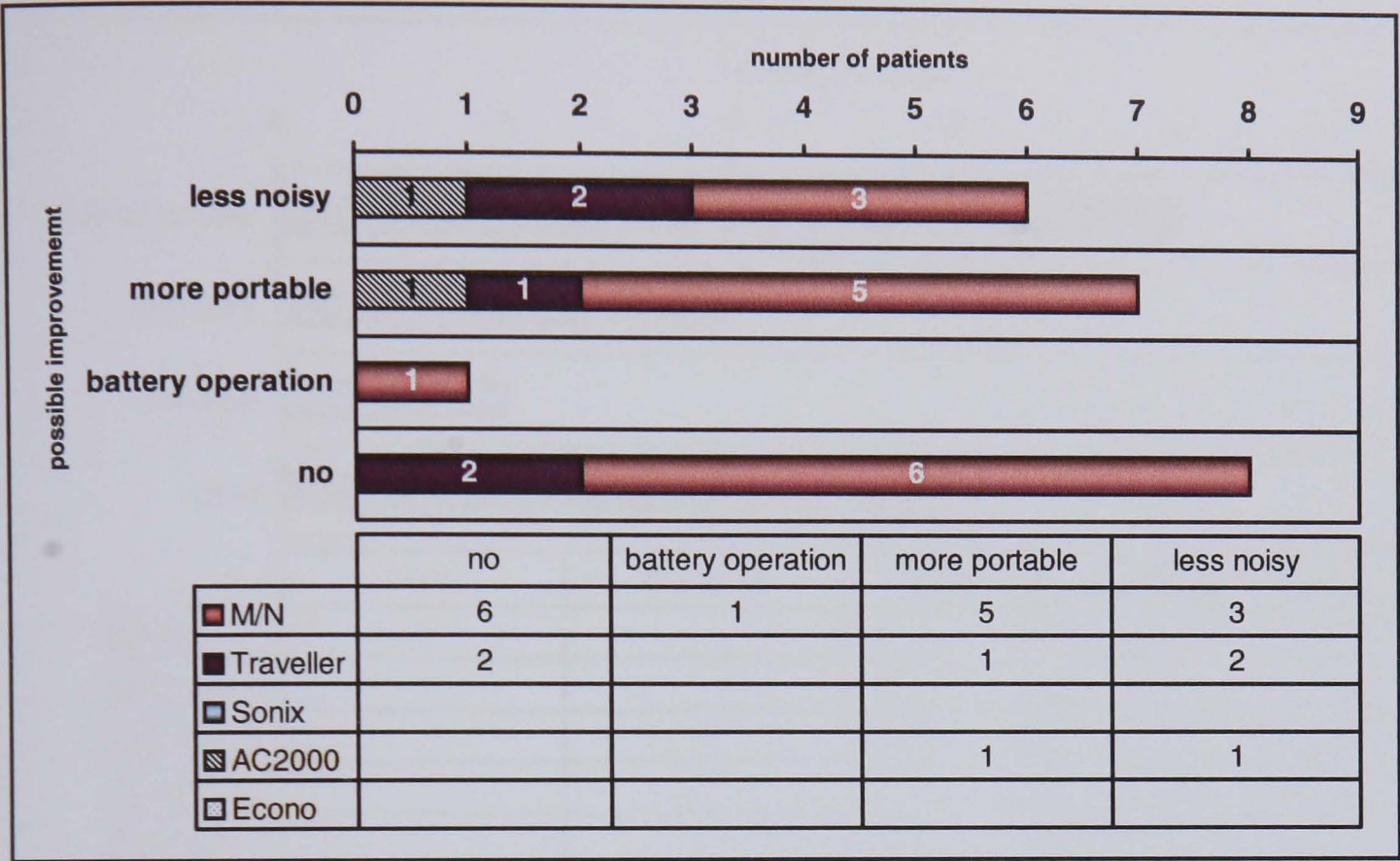
Respondents	Examples
Econo : 1	Oxygen
Traveller : 1	Walking stick
Sonix :1	Maintenance (when no transport available)
Trave : 1, M/N : 3	Unanswered

19 respondents provided 19 ticks. 36.8% of ticks were 'yes' and 63.1% of ticks were 'no'.

11 respondents (M/N: 6, Traveller: 4 and AC2000: 1) did not answer. The above table suggests that suitable equipment can be designed within their treatment area and also other possible areas.

Q21. Could your equipment be improved & how?

No options were given.

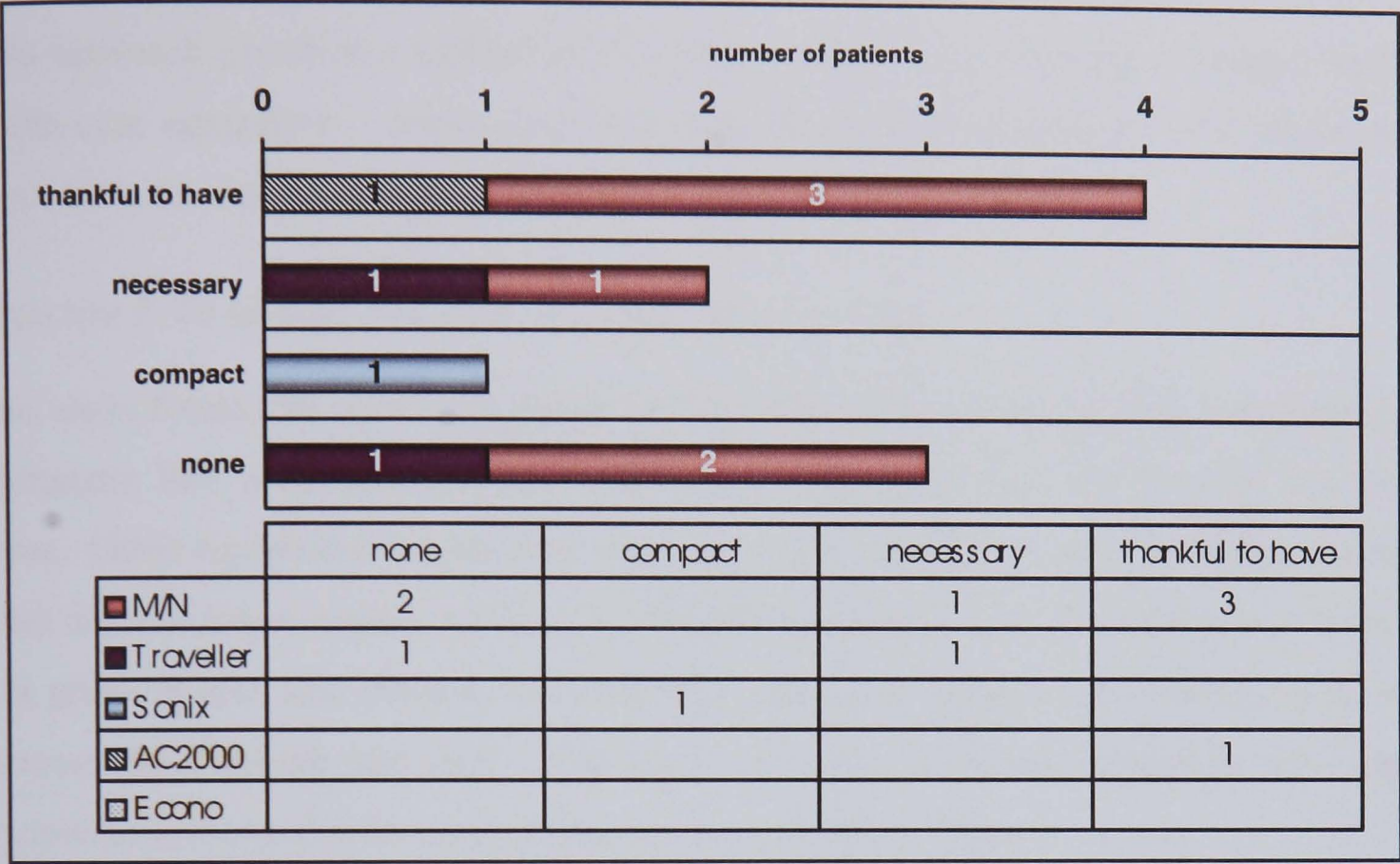


This was an open-ended question and content analysis was used to explore the answers. 18 respondents provided 22 answers. Among the 22 answers, 27.3% of answers related to 'less noisy', 31.8% referred to more portable and lighter, one respondent answered 'battery operation', 36.4% answers were 'no'. Twelve respondents (M/N: 6, Traveller: 2, Sonix: 2, AC2000: 1 and Econo: 1) did not answer.

It seems there is a design opportunity for increased portability of equipment and less noisy equipment.

Q22. Is there anything more you would like to say about the equipment you use?

No options were given.



This was an open-ended question and content analysis was used to explore the answers. Four respondents answered ‘thankful to have it’, two respondent answered very necessary, one respondent answered smaller and compact, three respondents answered ‘no’. 20 respondents (M/N: 12, Traveller: 5, Sonix 1, AC2000: 1 and Econo: 1) did not answer.

4.7 Overall findings of user surveys

This section discusses the overall findings of the user surveys. The results of four different group surveys are synthesised.

This approach provides a collection of critical opinion about the use of home-based health-care equipment. Processing this data allows a prediction of what might be required in the design of new equipment.

Objective 1. To identify treatment & equipment types used.

This study found that some equipment such as kidney dialysis equipment or respiratory equipment like nebulisers formerly only used in hospitals had now moved into the home. Other equipment for the same treatment is also used at home and patients expect other areas of home treatments to grow. The use of home-based health-care equipment is a growing area and patients are expecting additional home-based treatments to be increasingly available and used. The equipment used for home treatments and other equipment associated with the same treatments is listed in Table 4-5.

Treatment type	Equipment	Other equipment
Home haemo dialysis (HHD)	Gambro AK 90 AK-10 Cobe C2 Cobe C3	Water purifier Weight scale Blood pressure equipment etc.
Home peritoneal dialysis (HPD)	Baxter HomeChoice PAC-X Gambro PD 100 Fresenius	Weight scale Blood pressure equipment Stethoscope etc.
Home diabetes (HD)	Disposable syringe Humulin BD pen Novopen Monitoring system	Pen types of syringe Glucose monitoring devices Finger pricking devices
Home respiratory (HR)	Medix Nebuliser AC2000 Traveller Sonix2000 Econo	Oxygen Flowmeter

Table 4-5. Treatment & equipment types used

The majority of users were quite experienced patients and nearly half of them had used the equipment for over 3 years (see Table 4-6).

Treatment type	Less than 3 months	3-6 months	6months - 1year	1-3years	Over 3 years
HHD	4.4%	8.9%	11.1%	15.5%	60.0%
HPD	3.6%	21.4%	32.1%	28.6%	14.3%
HD	13.3%	13.3%	10.0%	20.0%	43.3%
HR			6.7%	23.3%	70.0%
Total	5.3%	10.5%	14.3%	21.1%	48.9%

Table 4-6. Period of using the equipment

Objective 2. To identify the nature of equipment user training.

For the best use of their treatment and correct management of the equipment etc., training was required. Most of the users received training before home use. It was also found that for the same treatment, hospitals are using different types of equipment and some are newer versions than others. This survey found that some treatments are quite complicated and the user needs to be well trained and this sometimes involves a long period of training which can be costly.

Treatment type	Percentage of people trained	less than 1 hour	1 day	1 week	1 month	1-3 months	3-6 months	over 6 months
HHD	100%			11.1%	24.4%	28.9%	33.3%	2.2%
HPD	100%		35.7%	64.3%				
HD	83.3% (100%)	72.0%	8.0%	12.0%	4.0%	4.0%		
HR	92.2% (100%)	69.2%	23.0%	7.7%				

Table 4-7. Training period

Regarding their first time feelings on using these types of equipment, nearly half of the respondents answered they had felt about 90% safe. Two possible explanations are that a longer period of training and experience had given them a feeling of safety through familiarity and the other is that they might have forgotten how they had felt when they first used the equipment. However, the 6 respondents with less than 6 months’ experience of using the home haemo dialysis equipment gave answers that were no different from other data given below.

Treatment type	Nervous 20%	20-40%	40-60%	60-80%	Safe 80-100%
HHD	4.4%	15.5%	15.5%	13.3%	51.1%
HPD		21.4%	14.3%	25.0%	39.3%
HD	16.7%	26.7%	13.3%	10.0%	33.3%
HR	6.7%	13.3%	3.3%	10.0%	66.7%
Total	6.8%	18.8%	12%	14.3%	48%

Table 4-8. First time feeling

The study found that sophisticated equipment such as home haemo dialysis equipment does not always gives nervous feelings. In comparison between haemo dialysis equipment and diabetes devices such as a syringe, there are big differences in terms of technology applied, in that one is very high technology but the other is not. But the respondents' perception about their first time feeling in use is different and the table shows that using a simple syringe makes patients more nervous than using haemo dialysis equipment. Psychological factors for the design of home-based health-care equipment are identified as an important factor for future design.

Objective 3. To identify opinions about benefits of use.

Many benefits of using equipment at home were identified. These are convenience, saving time, saving travel and safety (see Table 4-9). A variety of answers was given for the most pleasing feature of their equipment (see Table 4-10).

Treatment type	Convenience	Saving time	Safety	Saving travel	Etc.
HHD	30.1%	25.7%	4.4%	29.4%	10.3%
HPD	36.6%	25.3%	8.5%	22.5%	7 %
HD	42.6%	29.6%	16.7%	9.3%	1.8%
HR	46.5%	13.9%	18.6%	16.3%	4.7%
Total	36.2%	24.7%	9.5%	22.4%	7.2%

Table 4-9. Benefit from using the equipment at home

Treatment type	The most pleasing feature of the equipment	Percentage
HHD	Reliability	31.9%
	Saves their lives	14.9%
	Easy of use	19.1%
	Finishing the dialysis	6.4%
HPD	Time management	33.3%
	Function	25.9%
	Easy to use	14.8%
	Display	14.8%
	Mobile	7.4%
HD	Reliability	16.6%
	Ease to use	16.6%
	Simplicity	11.1%
	Disposability	11.1%
HR	Portability	39.1%
	Relief	30.4%
	Reliable	13%
	Always at hand	13%
	Easy to use	13%

Table 4-10. The most pleasing features of the equipment

Other benefits and pleasing features were also identified as follows;

	Other benefits & pleasing features
HPD	More independent life style-10h/week
	Ability to lead a new normal daily life & being able to take it on holiday etc.
	Control over own treatment.
	Feeling better than I did with the other methods of dialysis i.e. Haemo dialysis & CAPD.
	Can use overnight
	Days are completely free
	Keeps me alive
HHD	Better life style
	Control of illness
	At home, it is psychologically better. You are not associating with 'sick' people
	There are no pleasing features, it is a necessary evil. It must be used to keep me alive!
	Dialysis is pleasing
	When I first trained on the C2 it was user friendly in that it is painted on the front with blue & red lines & arrows to indicate positions of venous & arterial lines. Alarm lights etc. are easy to understand & if it alarms it is a matter of systematically looking for the problem.
	Sensitivity
HD	The Cobe C2 is not computerised. Any adjustments can be started out by the operator.
	No pain
	Good result
	Easy to carry
HR	Connect to computer
	Do not have to go into hospital as often
	It helps to remove sterol congestion
	240 volt
	Lack of admissions

Table 4-11. Other benefits and pleasing features

The use of equipment at home gives many benefits and pleasing features to patients. Each types of equipment has good and bad points in terms of use but if designers knew what patients wanted and needed, the benefits and pleasing features of using the equipment could be increased.

Objective 4. To identify opinions about problems of use.

Many problems were identified, such as set-up, control, maintenance and other points. The table shows that even with simple products like injection devices, a quarter of users had also had experienced problems with the products. (see Table 4-12)

Treatment type & respondents	Set up	Control	Maintenance	Others	No
HHD : 34/45	39.1%	28.3%	17.4%	15.2%	11/45
HPD : 20/28	40.7%	33.3%	11.1%	14.8%	8/28
HD : 8/30	12.5%	50.0%	12.5%	25.0%	22/30
HR : 9/30	44.4%	22.2%	22.2%	11.1%	21/30
Total : 71/133	37.8%	31.1%	15.5%	15.5%	62/133

Table 4-12. The problems of using the equipment at home

When they had experienced these kinds of problems, firstly respondents overcome these problems by practice, use and experience, they tried to contact technicians, nurses and manufacturers, but hardly any of the respondents had referred to handbooks or manuals.

Treatment type	Practice	Inquiry	Hand book	Etc.
HHD (34/45)	41.2%	47.0%	8.8%	2.9%
HPD (20/28)	30.0%	55.0%	15.0%	
HD (8/30)	62.5%	37.5%		
HR (9/30)	77.8%			22.2%
Total	45.1%	42.3%	8.5%	4.3%

Table 4-13. Overcoming the problems

Varieties of answers were given for the most frustrating feature of the equipment.

Treatment type	The most frustrating & annoying feature of the equipment	Percentage
HHD	Time spent	23.5%
	Cumbersome	20.6%
	Size / space	14.7%
HPD	Cumbersome	37.5%
	Size /space	12.5%
	Lack of mobility	12.5%
HD	Needles	22.2%
	Cumbersome	16.7%
HR	Noisy	30.8%
	Lack of mobility	30.8%

Table 4-14. The most frustrating & annoying features of the equipment

Many problems and the most frustrating feature of the equipment were identified. Clearly, these are features that could be considered in the design of improved equipment.

Objective 5. To identify opinions about availability/ loan/ ownership.

It was found that most of the equipment for the respondents' treatment was provided by hospitals. Haemo dialysis equipment and peritoneal equipment was provided by hospitals and no one had their own equipment at home. If the equipment was not available 75% of HD users, and 66.6% of HR users preferred to buy and 26.6% of HD users and 26.6% of HR users purchased their own equipment. This means that even though the area for home use is increasing it does not mean every one is buying the equipment privately. The main actual customer with regard to ownership of equipment is the hospital rather than the private user.

Treatment type	Yes	No	Yourself
HHD	The equipment was provided by hospitals.		
HPD			
HD	75.0%	25.0%	26.6% (8/30)
HR	66.6%	33.3%	26.6% (8/30)

Table 4-15. Preferences

Many of the equipment users had other equipment. The HHD users preferred to use more modern equipment and expect better treatment, but most of them could only have equipment limited within each hospital’s budget. There are gaps between the older and younger age groups in terms of preferences: this point, the preferences of different age groups could be taken into account in the design of equipment future. For example, the older age group wanted to use an old style control panel because they are used to using that style but a younger age group preferred to use a modern computerised style of equipment.

Treatment type	Yes	No
HHD	49%	51%
HPD	32.1%	67.8%
HD	16.7%	83.3%
HR	7.4%	92.6%

Table 4-16. Using other equipment

Objective 6. To identify opinions about any possible improvement.

About 55% of user (100/133) answered scope for more home-care treatment. It was found that suitable equipment could be designed within their treatment area and also other possible areas. Therefore home equipment treatment can be possibly expanded.

Treatment type	Yes	No
HHD (37/45)	37.8%	62.1%
HPD (21/28)	23.8%	76.1%
HD (23/30)	47.8%	52.1%
HR (19/30)	36.8%	63.1%

Table 4-17. Scope for more home-care treatment

The users expected to improve their equipment for several reasons.

Treatment type	Percentage	Expecting improvement
HHD	28.6%	Portable / smaller
	25.0%	Easy to control
	25.0%	Replacement
HPD	36.3%	Portable /smaller
	18.2%	Less cumbersome
	18.2%	Less noisy
HD	15.8%	Finer needles
	10.5%	Etc. (faster /measurement)
HR	33.3%	Less noisy
	38.8%	Portable

Table 4-18. Possible improvements

As discussed in this chapter home-based health-care equipment produced many problems. Many users were found to have problems with the controls, set-up, maintenance, etc. It follows, therefore, that the specific study of home-based health-care equipment might have a wider relevance to the general area of designing more effective new products.

The next chapter presents the results of interviews with hospital staff.

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Chapter 5

Interviews with Hospital Staff

CHAPTER 5. *INTERVIEWS WITH HOSPITAL STAFF*

5.1 Introduction

This chapter presents the results of interviews with hospital staff, regarding the use of equipment. The aim of the hospital staff and patients surveys was to discover deficiencies in using the equipment. In terms of use of equipment, although the equipment was used in different places, the actual users included hospital staff. Therefore, in addition to the patient questionnaire surveys from Chapter 4, hospital staff's views on using the equipment are discussed in this chapter. Although the staff responding were not all involved with home-based health-care patients, their views on equipment controls, etc. were useful. A study of medical equipment at an ITU (Intensive therapy unit) is included because this unit had been the subject of an article in 1986.

Section 5.2 is a general discussion of the staff interview objectives. Section 5.3 discusses the renal unit survey. Section 5.4 discusses the Dorset Healthcare survey. Section 5.5 discusses the study of the intensive therapy unit.

5.2 General discussion of the survey of hospital staff

This hospital staff survey was conducted by means of interviews at hospitals. Home-based health-care equipment is used (operated) by patients and their carers, nurses, technicians etc. and they are trained by hospital staff who had special training provided by the manufacturer. This survey involved a total of 13 staff working at five hospitals in the UK, namely, Oxford Churchill Hospital, Birmingham Queen Elizabeth Hospital, Leicester General Hospital, Whipps Cross Hospital and Dorset Healthcare HNS Trust, and one medical research unit at the University of Central England (see Table 5-1).

The answers to the questions to staff were analysed in order to achieve the following five objectives.

1. To identify trends and types of home-based health-care equipment.
2. To explore the nature of user training for home-based health-care equipment.
3. To gather opinions about control mechanisms.
4. To identify opinions about problems of use.
5. To explore opinions about any possible improvements.

Table 5-1. Hospitals & interviewees

Hospital	Name	Position
Oxford Churchill Hospital (OCH), Renal Unit	Mr. R. Bühler	Senior Nurse Manager
	Mr. N. Torgerson	Head Technician
	Mr. R. Lambourne	Senior Technician
Birmingham Queen Elizabeth Hospital (BQH), Renal Unit	Mr. J. Harrison	Senior Technician
	Ms. R. Duncan	Community Nurse
Leicester General Hospital (LGH), Renal Unit	Ms. T. Smith	Nurse Manager
Dorset Healthcare NHS Trust	Ms. O. Rowe	Physiotherapist
	Ms. T. Compton	Occupational Therapist
	Ms. C. Rosset	Rehabilitation Assistant
	Ms. C. Close	Sister (Day Hospital)
	Ms. Y. Davey	Staff Nurse
University of Central England, Medical Design Research Unit (Previously Worked for London Royal Hospital, Clinical Department)	Mr. C. Ramsden	Director (Medical Clinical Engineer)
Whipps Cross Hospital, Intensive Therapy Unit	Dr. M.R.Hamilton-Farrell	Consultant Physician

The Whipps Cross Hospital intensive therapy unit study had the additional objective of making a comparison with the problems described in 1986.

The following sections provide the results of the interviews, divided into three parts;

- staff at renal units,
- staff at the Dorset NHS Trust
- and staff at the intensive therapy unit (ITU) at London Whipps Cross Hospital.

5.3 Interviews with hospital staff in renal units

This section provides the results of interviews with six people in three renal units (see Table 5-1). A renal unit covers four areas, which are, pre-dialysis patients, haemo dialysis patients, CAPD (Continuous Ambulatory Peritoneal Dialysis) patients and transplant patients.

5.3.1 Types of equipment and patient types

Smith (1996), Nurse Manager at Leicester General Hospital, claimed that there is a large increasing dialysis population and there is a variety of equipment available that the renal unit can provide for patients at home.

The different types of dialysis equipment are described in Chapter 4, Section 4-3 and 4-4. Duncan (1997), Community Nurse at Birmingham Queen Elizabeth Hospital, stated that hospitals provide education, psychological and physiological care and social support to

patients in the build-up to when they need dialysis and help them make informed choices as to what treatment they wish to have. At the pre-dialysis stage, where the unit has ‘education days’, patients choose the type of treatment they want, either HD (Haemo Dialysis) or PD (Peritoneal Dialysis).

Each hospital has a different proportion of home patients for HD and PD. Home dialysis machine users total 7.4% of total patients (see Table 5-2). Table 5-2 shows that each hospital has a different percentage of dialysis machine users. Home haemo dialysis equipment (HHD) users total 8% of those using haemo dialysis and the rest of the patients come in to the unit (HosHD). 6.5% of PD patients use the Automated Peritoneal Dialysis (APD) machine in which about 20 litres of fluid is pumped through patients overnight for 10 hours mainly while they are asleep. The remainder of PD patients 93.5% are on Continuous Ambulatory Peritoneal Dialysis (CAPD), which requires four bag changes a day and they do not require any machine.



Hospital	HD		PD		HD+PD	
	HosHD	HHD	CAPD	APD	HosHD+CAPD	HHD+APD
Leicester General Hospital (LGH) - 450 Patients	200 (100%)		250 (100%)		450 (100%)	
	177 (88.5%)	23 (11.5%)	237 (94.8%)	13 (5.2%)	414 (92%)	36 (8%)
Birmingham Queen Elizabeth Hospital (BQH) - 500 Patients	300 (100%)		200 (100%)		500 (100%)	
	293 (97.7%)	7 (2.3%)	194 (97%)	6 (3%)	487 (97.4%)	13 (2.6%)
Oxford Churchill Hospital (OCH) - 500 Patients	350 (100%)		150 (100%)		500 (100%)	
	312 (89.2%)	38 (10.8%)	130 (86.7%)	20 (13.3%)	442 (88.4%)	58 (11.6%)
Total Patients (%)	850 (100%)		600 (100%)		1450 (100%)	
	782 (92%)	68 (8%)	561 (93.5%)	39 (6.5%)	1343 (92.6%)	107 (7.4%)

Table 5-2. Types of patients in renal units

Oxford Churchill Hospital is involved with changing the C2 haemo dialysis machines over to the AK 90. At Birmingham Queen Elizabeth Hospital, the unit used to have the Gambro AK 100 and C2 (Cobe 2) machines for HD treatment but they have now changed to the Gambro AK 90. Torgerson (1997), Head Technician at the Renal Unit, Oxford Churchill Hospital, claims that the machines will keep going as long as the parts are replaced. The unit keeps the C2 machines for between 10-15 years. The reasons for change are usually due to obsolescence rather than the equipment wearing out. The oldest C3 machine is about nine years old. The newer machines are much more technologically sophisticated.

The ages of patients vary. At Birmingham Queen Elizabeth Hospital, for example, their youngest patient is in her 20s and she is on the PD machine. The youngest patient on haemo dialysis is in his 40s. The oldest is around 65 years old.

5.3.2 Trends of equipment

Some of the major design trends over the last five years are that the current machines are much smaller than earlier models and it is more easily understood than before (Smith, 1996; Duncan, 1997; Harrison, 1997).

Duncan (1997) claimed that although 85% of patients who use dialysis machines are on the HD machine, the number of patients picking up on the APD machine is increasing because the machine works very quickly and is easy to use. She also agreed that the newer machines are much more compact. The machines that the PD patients have, actually fit into a suitcase and they can conveniently take them away on holiday. There is a manufacturer who has developed a bag warmer which is powered from the cigarette lighter socket in a car, so that the car battery will warm the pad and the patient can warm the bag of fluid in the car (Smith, 1996). They are more compact and easier to carry around than before, but they are still heavy.

There is one portable haemo dialysis called 'REDY' machines, which a patient can take on holiday for up to three weeks. At present the equipment available is for patients who can only dialyse themselves for relatively short periods of time. The problem is that the water used must be purified before they can be dialysed on the equipment. A significant

feature of the 'REDY' machine is that there are special filters to purify the water. A problem is if the water is purified then they need to go somewhere, the patient must drain away this purified water. Another problem is that patients have to transport the machine upright, otherwise concentrated fluid may interfere with the electronics inside. Additionally, if patients take the equipment away on holiday and then have a problem, the technicians are not available to deal with it.

Harrison (1997) claimed that the more modern machines are easier to handle and when the machines produce errors they start to communicate with the patients. The older type machines have lights with text to say what is wrong. Patients had to interpret what the problem was. So the older machines tended to require a lot of interpretation from the patient. For example, when patients got a warning light, they looked at that light and then the patients had to check what was wrong. With the newer type of machines, like a Gambro AK 90, the machine immediately tells what the problem is and makes suggestions as to what the patient should look at or ask for technical assistance. This control interface is discussed further in Section 5-3-6.

5.3.3 Relationship with manufacturers for customers' opinions

Bühler (1998) claimed that the Renal Unit has regular contact with the manufacturer Gambro, and use such opportunities to tell the manufacturer how they feel the machine should be improved. In respect to the design of a new dialysis machine, he is not aware that they have been asked to become involved in the design of the machine as such but manufacturer representatives do go out and ask hospital staff how a new machine should be specified in terms of improved functions and deleted functions.

Smith (1996) claimed that manufacturers like Gambro work very closely with them, to make sure a machine does what it is supposed to do and to see how the design of the machine can be improved. For example,

If somebody in the renal unit comes up with an idea, they go to Gambro with it. It could be something simple like, 'this light would be better if it was square and not round', and within a couple of weeks Gambro will have modified it (Smith, 1996).

5.3.4 Purchase of equipment

According to Bühler (1998), on peritoneal dialysis, they have 2 or 3 machines which were donated by charity, but the rest of the machines belong to the company which also produces the fluid, and the hospital pays for the treatment. The renal unit does not buy the machines, but pays a fee for the treatment for automated peritoneal dialysis (APD) and therefore pays for the use of the machine at the same time.

The APD machine used by Birmingham Queen Elizabeth Hospital is HomeChoice, which is a Baxter machine. Purchasing is all done by the Private Funding Initiative (PFI). This means the machines are hired or bought and hospitals have a contract with the company and the company maintains the machine and hospitals train the patient. If the patient has an operational problem with the machine, they ring Baxter direct (Harrison, 1997).

For haemo dialysis the machines are owned by the hospital and some of machines might have been paid for by a charity but the renal unit bids for the majority of the machines internally within the Trust to buy for new patients. To replace existing machines they again have to bid to the Trust to get the money, so, in effect, the Trust buys the machines.

Hospitals do not charge the patients who use kidney dialysis machines at home, even though the kidney dialysis equipment which is given to patients to take home is extremely expensive. Peritoneal dialysis is different regarding the mechanism it has for the type of dialysis, in that the mechanism requires a catheter where the water runs in and out. The machine allows pure water to run in, leaves it there, and then lets it out. That machine must be used every single night. The cost of a machine for peritoneal dialysis is £7,500 compared to the £16,500 for haemo.

Purchase decisions are made by senior staff in the renal unit, for example, the senior nurse manager. However, technicians also have a lot of influence in these purchase decisions. According to Smith (1996), the unit has a team of technicians who buy equipment for them, look after all the equipment and go to patients' homes to maintain the equipment, and monitor its use. The patients themselves usually do not recognise that anything has gone wrong (Smith, 1996; Bühler, 1998).

5.3.5 Patients' training

Smith (1996) believes that although the machines appear very complicated patients can be trained to use them. Training periods depend very much on the patient and the helper who is also being trained. There are differences between home dialysis, haemo dialysis and peritoneal dialysis. For home peritoneal dialysis, using a machine, the training could take anything from 2 days to 7 or 10 days, but on average the patient would be in for 3 to 4 days for peritoneal dialysis training with the machine.

For home haemo dialysis the training time required is much longer, and alongside the training, there might have to be some home conversion. The home, or a room might have to be adjusted and patients might have to seek building permission for this work. Otherwise, this goes on at the same time as the training.

On average, to train a patient for home dialysis can take from 6-8 weeks to 3-6 months, but 3-4 months is typical. According to Harrison (1997), the training can be split into two areas. One is learning to inject the needle, or 'fistula', which can take up to two months for the patient to become competent. In fact for the fistula, for the blood vessel, to develop in size – (if a patient starts from new the blood vessel has to develop in size and that takes time) it might not be possible for the patients to needle themselves to start with. The other area involves the machine operation. This used to take about three months to get somebody competent with working it, especially with older machines (Bühler, 1998; Torgerson, 1997).

Clearly the training period is dependent on a patient's personal ability and experience. For example if someone has been trained on a similar machine before, he/she could go home within a week (Harrison, 1997). The machine has capability to be used with a computer, which will monitor what is going on in the machine, but the renal unit does not use this facility (Smith, 1996; Bühler, 1998).

5.3.5.1 Priorities on training

The priorities are linked to ensuring that the patients are able to position needles, and have access to, and be able to connect to the machine; also that they are capable of operating the machine, operating the treatment, finishing the treatment, and maintaining safety in

relation to the machine. It is particular important at all times for the patient to have the ability to prevent infection, and safely operate and handle the machine, because potentially, if patients programmed the machine wrongly they could make themselves very unwell.

Additionally, the carer or partner has to be trained to aid the patient and to be there as a backup at all times, since patients have blood coming out of them or they can faint or have a heart attack and so, the partner has got to be there to take over. In other words, if there is a problem there must always be somebody there who can be called to help. The majority of home patients, however, manage very well, otherwise the staff would not allow them to be at home on the dialysis machine.

Just before the patient is ready to go home, the training includes what to do if something goes wrong with the machine, if some unforeseen problems arise, what to do when dealing with emergencies, if patients have a power cut or a water cut. Patients also get some very basic training on how to maintain the machinery and the ancillary items, such as the water treatment. They also get some training in how to sterilise and clean the machine at the end of each treatment.

5.3.5.2 *Home treatment*

All of the patients that are on machines at home much prefer to be treated at home. These patients would not want to come back into hospital for their treatment because they are more in control of their own lives (Duncan, 1997). The advantages of using a haemo dialysis machine at home is that a patient can choose whenever they want to dialyse and are not bound by having to keep an appointment two or three times a week to come in to the hospital. On the other hand, if the machine is used in a hospital, it can be kept in use all the time, three or four times a day, 7-days a week, whereas at home it can only treat one person three times a week, and the rest of that time it is standing idle. This is a major economic problem for hospitals (Duncan, 1997; Smith, 1996).

Duncan (1997) believed that when patients first go home, they are usually accompanied by nurses on their first day to make the patients sure of what they are doing. Patients can find it very frightening to be at home the first time for their first self dialysis. Sometimes, on their next session, nurses visit the patient, but in the first two weeks when they dialyse six times within those two weeks, nurses probably go for about five of those times.

Usually, patients have got over the problems with inserting the tube to connect to the machine (lining) before they go home because they have done it so many times before (see Table 5-4 process1 and Figure 10-5). Usually the main problem is patients' lack of confidence in themselves, when they are on the machine, for example how to cope if any alarms go off. Nurses visit the home haemo patients as regularly as they require and at least once a month to take regular blood from them.

For home haemo dialysis treatment a water system installation is required, which can be attached to the wall of the patient dedicated accommodation. A technician fits Reverse Osmosis (RO), the water purification system, before the machine arrives. So, patients have to have relevant plumbing done in the house and obtain a water container. This costs about £3,000. The RO system operates with a membrane filter which costs about £400 and lasts about four to five years. So there is a significant cost implication for water treatment in addition to that of the dialysis equipment (Harrison, 1997; Togerson, 1997).

5.3.6 Control systems for haemo dialysis machine operation

The HD machine could technically be used at home but this is not considered appropriate without 3-4 months' training, because of its complexity or risk of 'doing the wrong thing'. However, understanding how to control the machine is a crucial point of training and, obviously, the proper use of the haemo dialysis machine is needed by patients. Therefore, this section discusses how 4 different HD machines interface with patients.

This section starts with an overview of the main control process, and then investigates how each machine approached the control interface with patients according to its main control process. The end of this section is a summary.

5.3.6.1 Overview of main control process

Haemo dialysis machines in operation continuously remove, purify and return blood to and from a patient whose kidney functioning is faulty. To achieve control of this process, the different machines have different control interfaces for all major adjustments.

Table 5-3 shows the main control process for four different HD machines and how patients need to operate them. The process is divided into four parts. The first part is

preparation, the second part is preparation for dialysis, which is the process before actual dialysis, the third part is the actual dialysis procedure and the final part is post dialysis.

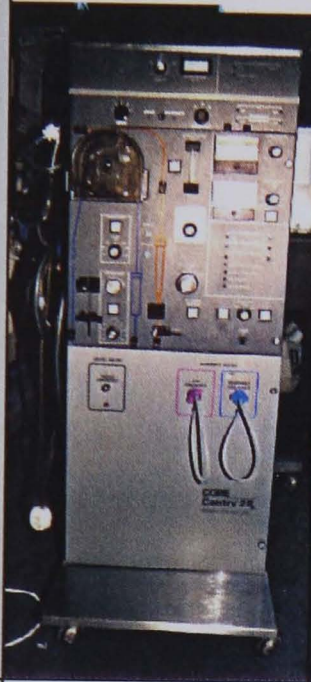

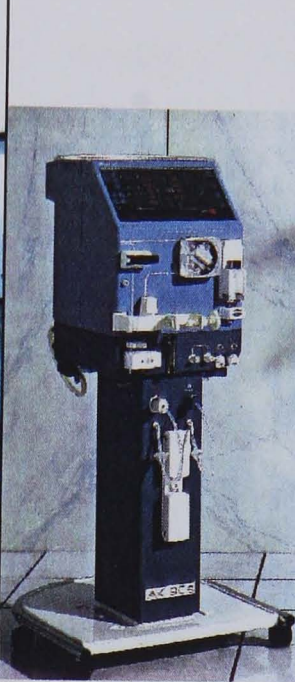
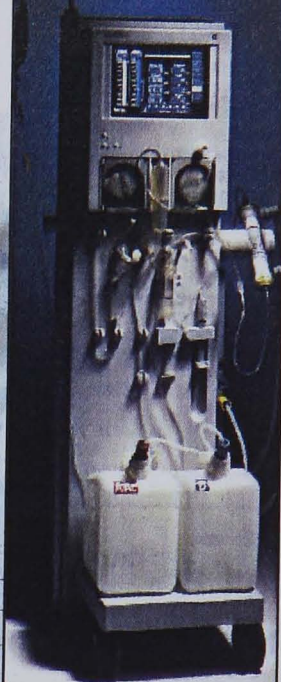

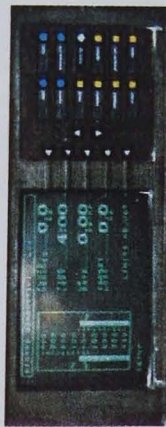
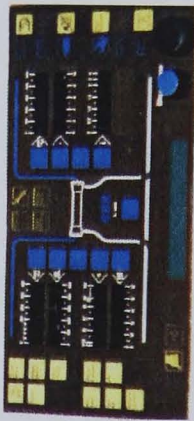
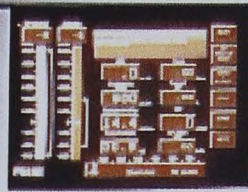
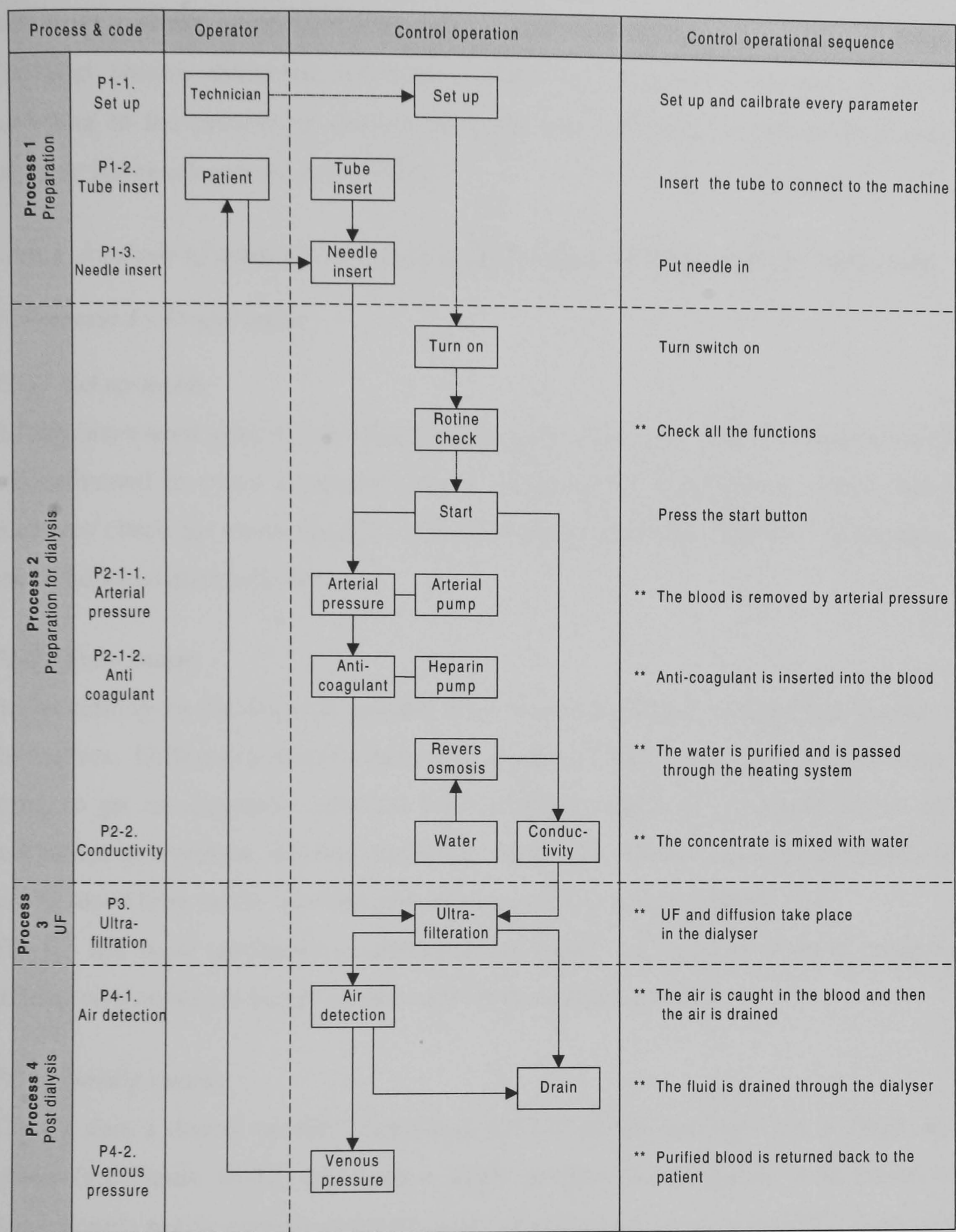
Process			C2	C3	AK 90	Althin
Haemo dialysis machines						
Process 1 Preparation	P1-1 Set up (Calibrate)		By technician	Automatic	Automatic	Automatic
	P1-2 Tube insert		Form of coil tubing	Cartridge format	Tube in chamber	Tube in chamber
	P1-3 Needle insert		Double	Single	Single	Single
Control panels						
			90 ° Rotated - Anti-clockwise			
Process 2 Preparation for dialysis	P2-1 Blood removal	P2-1-1 Arterial Pressure	Display	Display	No display	Display
		P2-1-2 Heparin Pump	Knob control	Automatic control	Automatic control	Touch-screen control
	P2-2 Fluid removal (Conductivity)		No display	Gauge on screen	Bar graph	Number display on screen
Process 3 UF	P3 Ultra-filtration (UF)		UF takes place in dialyser by several parameters (Conductivity, arterial and venous pressure etc.)			
			Tube gauge	Gauge on screen	Bar graph	Number display on screen
Process 4 Post dialysis	P4-1 Air detection		Alarm with flashing light	Alarm with display on screen	Alarm with text display	Alarm with display on screen
	P4-2 Venous pressure		Graduated knob control	Gauge on screen	Bar graph	Number display on screen

Table 5-3. Control of four different haemo dialysis machines



—————> Blood flow line —————> Fluid flow line

** All parameters are displayed on the control panel and if any errors occur then alarms go off and the patient needs to adjust or control

Table 5-4. Haemo dialysis operational sequence

Table 5-4 shows the general operational sequence of the machine control process and what patients need to do in order to have HD treatment. The patients have to proceed with all parameters displayed on the control panel. The patient training involves how to

control the machine when the alarm is on.

The next section discusses control mechanisms in detail. Each part is discussed according to the process of dialysis and then each machine is compared in order to ascertain how each process is achieved.

5.3.6.2 Analysis of main control process (The codes, P1-1 etc., refer to Table 5-4)

P (Process) 1 - Preparation

P1-1. Set up needs

All machines need to be set up before handing on to patients. The C2 needs to be set-up and calibrated in every parameter for the treatment by a technician, whilst the other machines check up automatically since they already have pre-installed parameters and can be adjusted automatically.

P1-2. Tube insert

Before turning on the dialyser, patients need to set-up a blood tube and put needles in to themselves. Different forms of tube inserts are used. With the C3, the manufacturer was trying to get an alternative interface with cartridge format of tube insert which needed less patient intervention, whereas on the C2, Althin and AK 90 machines the patient has to put the blood lines on the machine and connect up the pressure monitor line.

The C3 has more automated consumer items rather than having discreet components floating on a continual length of tube such as the C2 and AK 90.

P1-3. Needle system

The C2 uses a double needle system and the rest of the machines use a single needle system (see Figure 10-5). Although a single needle system appears to be easier to use than a double needle system, problems were identified by Torgerson (1997) who claimed that '*It is quite nice on the single needle system that only puts one needle in the patient instead of two*'. But his patients do not use many single needle systems. When patients perform with the single needle they tend to have problems with the needles. So he recommends that single needles should only be used on patients who have a very good blood vessel for needle size.

According to Lambourne (1998), the C2 can do single needle but it has to have an extra box adapter which is a venous and arterial clamp which sits on top of the machine. This is connected by a cable at the back and is then connected to controls via a single clink-clunk box to fill chambers and phase back into the patients. One of the critical aspects in achieving efficient dialysis is maximising the blood flow. So there is a disadvantage in that, if patients use the single needle system they can only take out the blood for half the time and then return it for half the time, thereby cutting down the overall effective blood flow rate.

P2 - Preparation for dialysis

P2-1. Blood removal

P2-1-1. Arterial pressure

The AK 90 does not have an arterial pressure monitor but, Torgerson, (1997) suggests, the user can find it more useful to have a pressure display. If the needle is poorly sited, by juggling around with the needle as the blood flow is coming, they can watch the pressure and determine what the best position is for the needle in the piston.

P2-1-2. Heparin pump

Anti-coagulant is inserted into the blood when the pump detects blood in the system. To control this, the C2 uses a knob; the AK 90 and C3 are operated by automatic detection which also can be adjusted, and the Althin is controlled through the screen.

P2-2. Fluid removal

There is no conductivity control display on the C2 but the AK 90 has a bar graph display; the C3 has a gauge on screen and the Althin display has numbers on screen. Torgerson (1997) believes a conductivity display is not a very important fact for the patients. When the C2 machine was designed, this was one of the pieces of information manufacturer decided not to show to patients. A more important consideration was showing patients that the machine worked within a safe operating range.

P3 - Process in the dialyser

UF (Ultra-filtration) and diffusion take place within the dialyser. But all different parameters, such as conductivity, arterial pressure and venous pressure, are promoted to

work the dialyser. UF is displayed in different forms; the C2 uses a tube graph, the AK 90 has a bar graph and the C3 and Althin have numbers on screen.

P4 - Post dialysis

P4-1. Air detection

All the machines displayed air detection by having an alarm, namely, a flashing light with buzzer. The AK 90 also has a text display and the C3 and Althin also have displays on screen.

P4-2. Venous pressure

Venous pressure is displayed in different forms; the AK 90 by bar graph, the C3 has gauges on screen, the Althin's is numbered on screen and the C2 has a graduated knob.

5.3.6.3 Summary

This section has discussed the main features of the four different machines, and given an idea of four very different interfaces, three relatively modern ones and one older style. The C2 control system is made up of analogue circuits such as temperature conductivity board, temperature alarms, etc. The controlling of the other machines is mainly by computerised software.

All the HD machines in this survey have a different approach of control mechanism. Concerning the AK 90, the screen enables a clearer message to be sent to the patient. For example, it has different indicators which come up at different times, whereas the C2 gives no options there. The C3 can give very specific messages. For example, one of the messages that it can give is if the pump is in the wrong position, and it will alert the user to it. The Althin machine is a screen interface so it has a very similar behaviour to the C3, although the Althin uses a touch screen. Where the C3 will use different buttons, the Althin will label buttons according to the screen, so if the screen changes, then it gives different labels to the buttons. The Althin machine operation is all done through soft keys on the screen. Patients have to operate only four keys which are on the screen of the Althin.

The HD machine has complicated processes and patients have to anticipate and manage all the different factors. The newer machines are easier to control than the older ones. But there are still difficulties in controlling the machines (Torgerson, 1997).

Each machine has its own separate character of control indications which patients found complicated and difficult to understand. For example, the AK 90 has several indications. A green light indicates that the dialysing fluid is safe and is going through the dialyser. If the machine determines that the dialysing fluid is not safe, it will keep alarming, and bypass the dialysing fluid so it does not go through the dialyser and that light will then become orange. Torgerson (1997) claimed,

That is just as self-explanatory as a pretty picture and I wonder how much is marketed on the pretty picture and how much is real user friendly. Although the AK 90 machines work quite well, the control interface seems a bit cluttered to me. There is a lot on there and if you read through the operators manual, it is sectionalised and you can see that but if you look at the machine those sections are not very obvious.

In contrast, the C2 simply has an LED to indicate that it is in bypass mode.

For home dialysis the machine has to be very user friendly. So, when an alarm goes off the problem has got to be readily identifiable. Patients need to manage the control mechanism. Some display functions are useful but some functions do not need to be known by patients. It was also assumed that HD equipment designed specifically for hospitals should actually be redesigned with domestic use in mind because usability is a problem. There are a lot of problems with machine errors. It might be possible to disable some functions or to have a different panel which patients could put on that would blank out a lot of the displays, as on some photocopiers, where patients just disable the adjustments.

As discussed above, HD machine control interfaces are complicated and difficult for patients to understand. Several factors discussed in this section are considered for the new HD machines at home but among them, ease of control and simplicity are the most important factors.

5.3.7 Peritoneal dialysis machine operation

The peritoneal dialyser uses a fluid bag and a line tube system. Patients take a bag of fluid running into their abdomen through the PD machine. If patients took cold fluid it would cause a state of physical shock, so patients have small bag warmers which are kept and monitored.

For the CAPD treatment, in the day-time, patients need to do a bag change before they go anywhere. They have to find somewhere at lunchtime or tea time, and do another change before they go to bed.

Patients with APD have all the bags on top of the peritoneal machine and patients fix themselves up to the machine and during the night while they are asleep. That machine allows fluid in and then it clicks over and allows the fluid to drain out. So it is much more gentle than a haemo dialysis machine and patients can dialyse at night whilst they are asleep, so in the daytime they do not have to bother about bag changes.

Duncan (1997) claimed that the HomeChoice APD machine is easy to control. It has a red button for stop and a green button for go and three buttons like keys on the computer to scroll up and down and enter. It is very easy to pick up its operation but patients require constant practice on it.

For the PD machines, first of all, nurses teach patients to do the programme and settings they want for their dialysis. Then, when they are ready to start to set it up with the different lines it tells them exactly what to do all the way.

The newer machines are definitely much easier than the old ones. It is a difficult thing to make simple. HomeChoice is really easy to use and I have trained patients on this in two days (Duncan, 1997).

Obviously training period depends on the patient themselves and how quickly they can pick it up.

As discussed in this section, peritoneal dialysis machines are less complicated than the haemo dialysis machines. One reason that most patients prefer to use peritoneal dialysis machines is that they are easy to use. This might suggest where HD machine design should go in the future. Ease in controlling the machine is one criterion towards accessing the patients' view of a dialysis machine.

5.3.8 Problems of using dialysis machines

Harrison (1997), Senior Technician at the Renal Unit, Birmingham Queen Elizabeth Hospital, claimed that people who take on home haemo dialysis take risks. Generally, home patients will keep that machine or that style of machine until they die or get transplants.

On haemo it is for their lifetime. It is giving patients' life back under their control. They are not waiting for taxis, they are not hanging around for someone to do things for them. They have their life back in control, although taking that on there is an in-built risk. On haemo, it is like someone stepping over a chasm 2,000m deep and 2ft wide. There is no problem, if you do it right. Do it sloppy, then you are down the chasm. You have to be very well motivated to have a life. There is a lot of good support. I know a lot of patients on dialysis who are totally on their own. They have to do it all themselves with no help. They are brave people (Harrison, 1997).

Torgerson (1997) believes that there are problems in design rather than any one specific problem that patients have with using the equipment. The majority of interviewees claimed that there are not many problems with the machine itself, but more with users. It is more likely through them not looking at what they are doing and missing part of the sequence. But Harrison (1997) pointed out that normally an engineer/technician would design the machine and they would produce knobs and buttons on the front which only an engineer/technician would understand. This shows that mechanically the machine does not produce problems but if the machine were designed to be easier to control, user error would be reduced. The design of the AK 90, for example, was very much influenced by an operator / user, either patients or nurses, and in training those machines have gone down better.

Apart from machine operation there are national problems. Duncan (1997) claimed that the renal unit needs more machines because the dialysis population is growing with the ensuing need for extra nurses and space. At the moment they have insufficient places to dialyse people and they do not have enough nurses to cope and they can only put patients who are actually having acute problems on machines because they are so expensive. Using the machines in a hospital environment does not cause many problems. For instance, when the patient is actually in hospital they feel much more secure because if anything happens there is someone to help them. At home, if anything happens, e.g. the machine clots or the pump stops, the difficult part is learning how to handle different situations when patients are on the machine (Duncan, 1997).

The major problem at home is access, getting blood out of patients and back in to them through the needles. The other problems are electricity and water because both flows have to be continuous. The machine takes in water constantly from the supply, so if the

water is at a lower pressure, then patients have problems. If the water or electricity fails, then the haemo dialysis machine stops. With haemo dialysis, if the equipment stops, the patient dies. There is a battery and memory inside which remembers the treatment details only for 20-30 minutes. If it turns off and then is turned back on again, the machine should remember and continue the programme.

There was a snag with the AK 90, in that it was a bit high, so when patients sat on a low chair, it was difficult to read the display. That has been remedied. Apparently there is now a corded remote with a screen with a limited display (Harrison, 1997).

Duncan (1997) believes that there is no problem with the actual PD machines themselves. According to Harrison, most of the problems with APD are the catheter/access which is the fluid getting in and out, and infections. Most of the problem is the water because it has to be continuous but the same problem of interruptions happens with the APD. Another problem is with the drainage system, when it is drained out. At the renal unit, staff have also had a few problems with the size of the bags.

5.3.9 Future improvements

Smith (1996) believed that there are several factors that should be addressed in the design of equipment. 1. The size of the machine: The machine is a big component if patients are to put a machine by the bedside. If the machine is big and cumbersome they cannot get it into a small back bedroom. 2. User friendly: If the machine develops a fault, for example, if the water overflows, 'in the hospital it is just get a mop and bucket but that would be more of a problem spilling on to a bedroom carpet, so it has got to be foolproof to use in the home'. The manufacturers have achieved this in a variety of ways, i.e. putting more alarms on the machine. 3. Transportable: The patient does not have to stay with the machine, the machine can be taken with the patient.

5.3.10 Summary of problems in using equipment

National problems were identified, in that hospitals are running out of places to dialyse people and they do not have the nurses to cope. So the renal units can only put patients on the machines that are actually having problems because the machines are so expensive.

There were not many problems associated with the machines in use in the hospital environments. More problems were found with home use. The table below lists identified problems of HD & PD machines. Each machine does not have all the problems which are presented below, but there are considerable problems which offer opportunities in the design of new dialysis machines. Concerning control mechanisms, the machines are complicated and difficult to understand by patients. Apart from that, the major problem at home is access, getting blood out of patients and back in to them through the needles. The other problems are electricity and water supply because both flows have to be continuous.

Design Criteria		HD machines	PD machines
Usability	Set up	✗	
	Access	✗	✗
	Control	✗	
	Maintenance	✗	✗
	Training	✗	
Appearance	Control lay-out	✗	
	Size	✗	
	Height	✗	
	Weight	✗	✗
Performance / Function	Noisy	✗	✗
	Safety	✗	
	Time spent	✗	✗
Environment	Storage	✗	
	Portability	✗	✗
	Water / electricity	✗	✗

Table 5-5. Problems identified (✗) in Renal Units

It was identified that the machines have few mechanical problems. Problems are to do with users not looking at what they are doing and missing part of the sequence, but if machines were designed to make modest and appropriate demands on the user, error should be reduced.

It was identified that normally an engineer/technician would design the machine and they would produce knobs and buttons on the front which only an engineer/technician would understand. On other hand, when the AK 90 machine was designed with influence from an operator, the user found it easier to use.

5.4 Dorset Healthcare NHS Trust survey

This section discusses the findings of interviews with 5 staff in the Dorset Healthcare NHS Trust in 1997. The interviewees are listed in Table 5-1.

5.4.1 Type of patients

The Dorset Healthcare NHS Trust (Dorset) predominantly deals with the elderly and very elderly. This involves heavy care and a whole host of diagnose and multiple diagnose for each patient.

5.4.2 Trends and types of equipment

Rosset, a rehabilitation assistant, explained that the equipment used at Dorset Healthcare in the past had been very much oriented to the person with the problem and had been fairly treatment specific. Rowe, a physiotherapist, claimed that community care used to be problem oriented, but now much more goal oriented so that if the goal is to help the carer at home or to help the patients themselves get out of the chair, then physiotherapy might help to build up the strength of their legs, rather than get a machine to do the work for the patients. So it is very different from renal failure where patients need a machine. But if it is still impossible for the person to get up out of the chair then some powered equipment might need to be provided.

Compton claimed that as an Occupational Therapist working as a team member, with very elderly and very infirm people to operate effectively they tend to look at powered equipment to assist daily living. With community care, the idea is that people return to their homes, supported by appropriate products that compensate for their disability allowing them to maintain their independence to a sufficient extent.

5.4.3 Customer opinions

One complaint according to Rowe and Close is that many manufacturers are trying to sell their products to hospitals or through other routes but they do not ask about how to improve their equipment so that it is better to use in the patients home, etc. Close agreed that, *'They're selling it, so they are telling you it's the best thing you can buy, because it's the salesman's job to do so'*.

Compton claimed that from her experience with Social Services more and more equipment is being used at home and there has not been adequate backup. There are firms where it is very difficult to exchange or repair their equipment. Therefore, companies that have better after sales services tend to be preferred.

5.4.4 Funding and purchasing of equipment

In the community hospital financial system to buy any expensive equipment, the community hospital staff (sister, occupational therapist, physiotherapist, etc.) have to refer to Social Services to pay for that equipment. Social Services base their decisions on financial criteria. For example, if a physiotherapist needs a hoist for the day hospital, she will get all the information first may even get people to demonstrate it. Then, she will put the proposal or request to her Manager/Budget Holder who would have the authority to say 'here is the money' but for a cheaper product. The equipment used on the ward is initially purchased through management. But most equipment is given to patients by the community hospital if patients ask for it specifically. Social Services have certain strict criteria and go out and assess, and if they have the equipment they would give it to that person.

The community hospital has an assessment system to lend equipment to patients for a while and then patients can purchase it. Rowe expressed that it is a dilemma for staff that the patients are bombarded all the time with TV and magazine advertisements, etc. Patients are tempted to spend a lot of money or get people to buy something very expensive for them before they have had advice from someone even though some equipment might be provided free through Social Services.

It would be a great incentive to them to be properly assessed. It is happening to a certain extent, because of physios in GP surgeries. However, a downside would be, would you have different advice from different places depending on who your GP is?

Another example is that some patients have been given a free wheelchair or other equipment, but have gone out and bought their own as well. The patients do not want to give the other one back and they are not using it and put in the garage as a 'spare'. Compton said that there is little staff can do since patients are entitled to it.

The community hospital in Dorset has an equipment store area for the basic equipment which the hospital can provide and anything else comes through the Social Services.

If Social Services can not always provide something, because in the community there is often a price limit, patients will pay for it themselves. It used to be the £100 mark. If it was more than £100 Social Services could not provide it. Rosset complained

Why don't they say 'if you put in the extra over £100 we'll get it' which maybe is a shame. They actually buy in bulk, can't they?

There are also the other funding sources which community hospitals, hospitals or patients may apply to. There are various charities, societies, etc. that the community hospital can access. But it is very difficult to find funds for different pieces of equipment. Compton claimed,

The current funding system is complex. It is very confusing for end users, patients. If we are confused, they must be!

She gave as an example that if somebody went on to environmental controls, curtains closing, etc., the money for that would come via the Regional Health Authority. If somebody in their home, needed a hospital bed, that would be via their GP or District Nurse.

Most of all, funding varies from region to region. Somebody could be in a certain area and get nothing, whereas for someone else in another area, it could be totally different.

5.4.5 Patients' training

Compton claimed that when they train patients to use equipment quite often they are not just training patients to use it, they are looking at patients' functional ability to use it.

Its not just a case of knowing how to use the equipment, it is a case of knowing how to function with it as well. To do it safely, if someone has a kitchen trolley, etc., to be able to use it properly. It's no use giving it to patients if the equipment is not going to be functional. So when they are using pieces of equipment with patients, they are showing patients how to use it safely.

She further explained that the elderly need to be introduced slowly to equipment.

If you say your husband can only go home if he's hoisted, the hoist is a frightening piece of equipment. So, what we do is get them into the hospital and say 'this is what it looks like. Just have a go without anybody in it' and gently introduce them.

In the past, for someone with a stroke we might have done this, for someone with Parkinson's we might have done that, but now we have to look at the patient in

their environment and the patient's carer is just as important because there are statistics to show that many carers die before the person who has the medical input. I think a good example of equipment which helps the carer is the wheelchair that has an attendant operated charge on it to assist the carer to push them up a hill. This is provided free.

5.4.6 Design problems

Many problems causing difficulties for staff or patients or carers were suggested by Compton, Rowe, Rosset, Close and Davey (1997) as follows;

1. Problems with usability

1-1. Control problem: With some of the bigger equipment like hoists, the castors on the hoists have to be substantial to take the weight of the person, but pushing it is difficult on some deep pile carpets. They found that it is difficult to get direction.

Hoists are not very nice because you're actually shoving the equipment and you're not actually touching the patient who is in the sling at the time. The wheel design could also be better as hoists are difficult to push (Compton).

1-2. Difficulty in maintenance: Close claimed that bath seats are extremely heavy and awkward for an elderly carer to put in the bath if it does not remain there.

When you take it out you've got a battle with the suckers.

2. Users' problems

2-1. Patients' physical problems: The Tens therapy machine was cited as having design problems. There are very small numbers on the Tens machine and quite often physiotherapists have to train an elderly spouse to put it on their elderly relative. Their eyesight and/or, their dexterity might not be good, but they have to go through with it even though they have physical difficulties.

2-2. Lack of consideration of patient activity:

The actual design of the Tens machine is small, it's neat and it works but it does not have a clip on it. There is no guard. It needs to have guards to suddenly stop turning up the amplitude (Rowe).

Rowe said, regarding a patient who had received treatment recently, that the electrodes were on the patient's left arm, and the only place that the machine could go easily was on the chair. The patient did not have a pocket but when the patient

had to go to the toilet,

Where does the patient put all this? It's very easy to pull on it. If it's used by a young person it's good because it's small and it's easy to put it in their pocket.

- 2-3. Psychological effects: Some patients feel that wheelchairs mean that they are unable to do anything, and yet if people have a wheelchair they can do so much more. So it is not inhibiting their independence, it is actually enhancing it, but they do not see it like that.

It's a little bit like a few years ago they didn't have to wear cycle helmets. Now they've become quite trendy so people will wear them. Sometimes it takes a government initiative like seatbelts in a car, sometimes the government have to say its law. You have to wear a seatbelt and that makes people accept it. But in the home its very difficult to get people to accept it (Rowe).

3. Performance and functional problems

- 3-1. Noise problem: The equipment used at home is quite noisy, for instance, stair-lifts and mattress elevators.

There was one woman who needed help. She lived on her own and she needed help lifting her legs into bed and there are leg-raisers that fit onto the side of the bed and literally lift her legs up, and then she could move them across. But it took so long and it was too noisy so she just did not bother (Rowe).

- 3-2. Safety: Some equipment can sometimes be dangerous if it is not used properly.

Rowe claimed

The firms are not being honest or not doing their job. For example, if someone had a stroke and they have these Tens machine and massage machines ... things that may be contra indicated.

Close agreed that the majority of people referred to them have fallen during transfers from the bathroom or kitchen, etc. She pointed out that the design of transferring equipment needs to consider how safely people can get on and off and can be assisted. Rowe added that there is a lot of equipment which people do not use correctly and causes more harm than good.

With Tens machines, for example, it is quite easy to knock the dial under the bedclothes, whip it right up and a patient can end up with wires hanging down which is dangerous and a patient could get something caught in them. It is particularly easy to get caught in the hoist. Another example is that some sophisticated equipment is

sold in Boots or Sainsburys and explanation on safe usage is poor and possibly unsafe or the equipment is inappropriately used.

3-3. Lack of mobility: Patients do not take their electric wheelchairs anywhere in the car because they can not physically carry them. People can put hoists in cars but such equipment tends to be very expensive.

4. Environmental problems

4-1. Lack of assessment: A ceiling hoist would only go up to a certain weight, but not every ceiling can take that weight. Compton gave the example of a lady who was just on the weight limit but could not yet use the ceiling hoist. Another patient was within the weight limit but the ceiling itself could not take the patient's weight.

4-2. To be used in conjunction with other things: Some equipment does not fit with other manufacturers' equipment. For example, the hoist legs do not go underneath the riser/recliner. Another example is some tables that are used in homes do not fit under all of the chairs. The manufacturers of some chairs have their own tables that just slot in. Davey believed that all the designs seem to be very individual.

Certain types of hoists cannot be used on riser/recliner chairs or hospital beds. I assume they've not been needs led, or some of them have, but so specifically they don't link in with other things.

5. Other factors

5-1. Expensive: Davey believed that a lot of equipment is incredibly expensive compared with the quantity of products manufactured.

Why do they have to be that much? I can see if you only make 20 they would be more expensive. It would be interesting to see what the mark-up was - how much they were manufacturing it for and how much they were selling it for.

5-2. Safety requirements: There was one person in an upstairs flat who needed to have a stair-lift. But he could not have it because there was not enough space. The stairwell might be too narrow, it might be a public staircase or it may need to conform to fire regulations. But a manufacturer is able to get stair climbers instead of a stair-lift which has passed all the safety requirements. Although Social Services would have provided a stair-lift free, they did not provide a stair climber, since they

considered it unsafe.

They won't even say, if the family say they'll put in the extra, they won't provide it. It's an anomaly. But Social Services wouldn't pay. It's useful to get Social Services on your side if you're a manufacturer (Rosset).

Davey and Rosset claim that all the designs at present seem to be very individual. They assume equipment has not been needs led, so specifically equipment does not link in with other equipment and other factors.

5.4.7 Future expectations

Close believes that much home-based health-care equipment is heavy, big and expensive, the 3 criteria which she believes are the barriers to greater and more effective use. In the near future, she also believes that more home treatment will be needed for people with strokes.

Improved factors and characteristics for equipment in the future as expressed by the interviewees can be summarised as follows.

Equipment needs to be cheaper, more reliable, easier to use, easier to follow up, more versatile, not cumbersome, more portable, more attractive, more durable, more adaptable to the home environment, lighter in weight, easier to maintain and more able to be used in conjunction with other equipment.

As discussed above there are many considerations which need to be taken into account for helping the quality of life for people in the future. The issues discussed in this Section 5-4, especially the machines discussed in this survey, will produce the criteria for the designing of home-based health-care equipment in Chapter 11.

5.4.8 Problems in using equipment

There are deficiencies in using equipment. Staff, patients or carers found difficulties, as follows;

Design Criteria		Identified problems
Usability	Control	Hoists with some deep pile carpets; it is difficult to get direction
	Maintenance	Bath seats are extremely heavy and awkward for an elderly carer to put in the bath if it does not remain there
User	Physical ability	Eyesight, dexterity
	Patient activity	Lack of consideration of patient activity
	Psychological effect	Some patients perceive that wheelchairs mean that they are somebody unable to do anything, and yet if people have a wheelchair they can do so much more. So it is not inhibiting their independence, it is actually enhancing their independence, but they do not perceive their situation in this way.
Performance / Function	Noise	Stair-lifts and mattress elevators are very noisy
	Safety	The Tens machines and massage machines can be dangerous if they are not used properly. Hoists can be unstable if used incorrectly.
	Mobility	Electric wheelchairs cannot be physically carried into cars etc.
Environment	Home assessment	A ceiling hoist only goes up to a certain weight, but not every ceiling can take that weight.
	Using with other equipment	Some equipment does not fit with other manufacturers' equipment, e.g. the hoist legs do not go underneath the riser/recliner. Every design seems to be very individual.
Other factors	Expensive	The products are expensive compared with the quantity of products which companies produce.
	Safety requirements	Social Services safety requirements are not understood by people in that although Social Services provide certain products they do not provide other products which have not been proved as being safe to use.

Table 5-6. Problems identified in using health-care equipment at Dorset Healthcare NHS Trust

5.5 Study of an Intensive Therapy Unit for comparison with 1986.

This section provides the results of interviews with Dr. Hamilton-Farrell, Consultant Physician, ITU (Intensive Therapy Unit) at Whipps Cross Hospital in London and Mr. Ramsden, Director, Medical Design Research Unit at the University of Central England, who previously worked for the Clinical Department at the Royal Hospital in London as Medical Clinical Engineer.

Whipps Cross was approached because of an article about its ITU, (Berman, 1986), 'The case for a holistic approach'. This article in Design magazine was critical of the design of hospital medical equipment. It therefore provided a basis for comparison with the more recent, 1998, situation. The interview with Ramsden is included because of his extensive experience.

It was assumed that the understanding of the changing needs of medical equipment would be useful to the design of home-based health-care equipment. According to Ramsden (1998), there are a lot of problems with health-care equipment, and it may be that a lot of the equipment normally used in a home would be the same or similar to equipment in hospital.

The results are presented in order to achieve the objective mentioned in Section 5-2. Further discussion is in Chapter 11.

5.5.1 Good and bad design, past and present

This section discusses medical equipment installed at the Whipps Cross Hospital ITU. It had been reported in 1986 that the worst examples of badly designed products were found in the Intensive Therapy Unit itself, where patients are to be found strung up to a mass of tubing, surrounded by machines. There is no system for stacking the equipment or dusting all the tubing and wiring.

In 1986, Hanson, Consultant Physician, being interviewed by Berman had remarked that '*all manufacturers are different, there's no uniformity, even of plug sockets*'.

Things had not changed very much. Hamilton-Farrell (1998) thought that the ITU was '*mess with massive equipment which used for treatment with their own purposes*'.

He added,

Going round with someone who has a design interest one can see just how appallingly laid out this whole department is, cluttered up with equipment, wires and flexes. We can't help it.

The equipment room shows how the equipment gets treated in real life. 'At the very least any equipment that is used has to be capable of being bashed, dropped, having things poured over it. All individual products are filling up the unit, even oxygen cylinders look unattractive even though they are necessary in case of gas failure in an emergency'.

It seems that most of the equipment used in the ITU has been changed since 1986 but still the problems remain and badly designed older machines are still in use. All products are individual, there is no uniformity and products are difficult to store.

There are very many different products installed in the ITU but this study is divided in to two sections, ventilators and other equipment. The criteria of good and bad are generated in Section 5.5.4.

5.5.1.1 Case study of ventilators

The ventilator is a standard piece of IT (Intensive Therapy) equipment. Berman (1986) claimed that one of the trickiest instruments to design is a ventilator which is used as a breathing apparatus, pumping air into the patient's lungs. There is a complex set of alarms on the machine that are triggered if the machine is turned off accidentally.

According to Hamilton-Farrell (1998), there are so many alarms working in the ITU environment but they all have to have a different tone. In other words, the noise the alarm makes is much more important than a flashing light. The noise draws attention to the machine and then looking at the machine can identify what the problem is.

In 1986, a number of basic design faults were reported.

One ventilator has a mute button, which delays the alarm system for two minutes, which was a good idea. But the button is so small that nurses tend to turn down one of the alarms instead, and run the danger of forgetting to turn it back on...On another ventilator, a vital switch used to vary the mode of ventilation is small, and difficult to use (Berman, 1986).

5.5.1.1.1 Study of older ventilators

- *Two older ventilators*

Two ventilators, made in Sweden, were compared by Berman (1986), the LKB Medical ventilator and the Elema Servo 900c ventilator as examples of a bad design and good design, respectively. On the LKB Medical ventilator, the controls could be reached by the patient, its enamel finish was peeling off and the knobs and dials were badly laid out and difficult to clean. *'The ventilator is a prehistoric horror... It is obviously designed with no attention to the effect its appearance might have on a patient'* (Berman, 1986).

Hamilton-Farrell (1998) remembered that the LKB Medical ventilator was unapproachable, that he had to excavate his way through all the pipes which are arranged in front of it. An oxygen meter was separated from the machine and was difficult to read. If something goes wrong with the machine they have to send the whole machine back. In contrast, in the newer operating rooms in the ITU, monitoring systems are being set up as an all-in- one box with modules that can be pulled out and put in, and they find that very helpful. So if anything goes wrong with one of the modules, they can pull it out and send it off to the manufacturer and carry on using the rest.

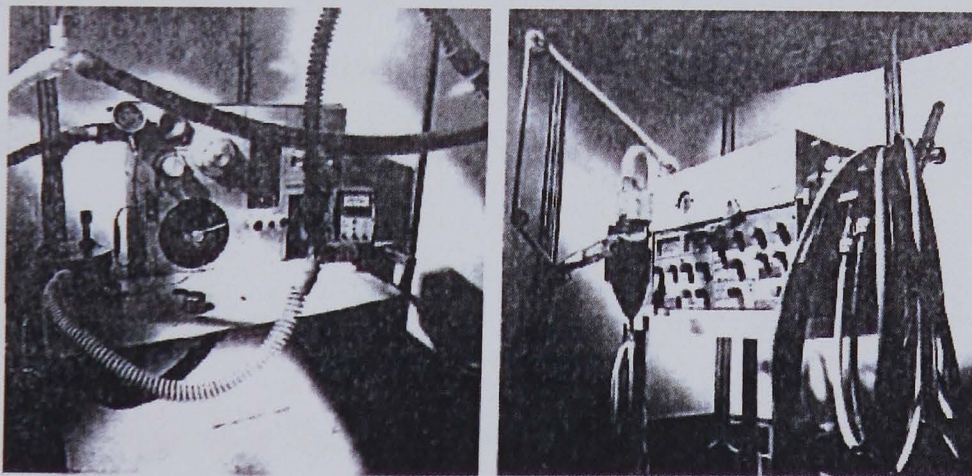


Figure 5-1. Ventilators - LKB Medical & Elema Servo 900c (Source: Design, March, 1986)

The Elema Servo 900c ventilator, which had been chosen by Berman as a well designed machine in 1986 is still there and much preferred by the staff in the unit. *'It works well, and, unlike the first machine, it is light and easy to manoeuvre'* (Hamilton-Farrell, 1998). He further claimed that from the user's point of view it has a relatively simple control panel which is quite good in that it incorporates some digital and some analogue settings. He believes each is useful in its own way. There are however, problems in that it is not ergonomically very efficient when bending down. He explained that there are a lot of

knobs and dials at the front and staff have to bend down to reach them. Furthermore, because each one is labelled with quite small writing, and sometimes the writing is underneath the knob, staff have actually got to bend right down to read it. He also suggested that in some way the labelling should be designed so that it can be more easily read or else the piece of equipment could be held at eye level.

The equipment is very robust but it has sharp corners. Hamilton-Farrell (1998) complained that he had hurt himself in the past bumping into it, whereas there are other ventilators in the ITU, which, rather than being in a big box are actually sloping, on a gradient. He considered that to be another good point of visual access; looking down on a panel which is arranged like that is much easier to use. He claimed that when something is designed in that way, somehow it is easier to manoeuvre around than if it is a big rectangular box with sharp corners.

The machine is supported on a stand which is potentially quite top heavy. A sturdy trolley, would probably be a better support, but if the whole thing is supported from the ceiling it would even better. He also found the gantry system which supports the airway connections, a little cumbersome. He suggested that switches or the little nuts that help to stabilise the position of the joints when the correct position has been selected, do not stand the test of time very well and can become loosened. He also suggested that the fresh gas supply hoses that are draped over other objects would be better suspended from the ceiling.

- ***Another older ventilator***

Berman (1986) reported that the attitude of the nurses in the unit to an Assistance Technique Medicate (ATM) ventilator which had been newly acquired at that time in 1986, from Assistance Technique Medicate in France, was that

If you ever need a ventilator don't use one of these. A measure of how well it has been designed is the fact that a screwdriver has to be used to switch it on or off.

The ITU does not have the ATM machine anymore, because it was so badly designed for operation. Hamilton-Farrell (1998) remembered,

Awful, absolutely terrible, a fantastic philosophy, very into electronics and you had to tie a screwdriver onto it and little switches are incredibly difficult to operate, and it was unsafe because people did not know which switches to choose on the

back of the machine so they just set it onto whatever it was before, and I think it did away with the advantage of the sophisticated machine because nobody knew how to set it.

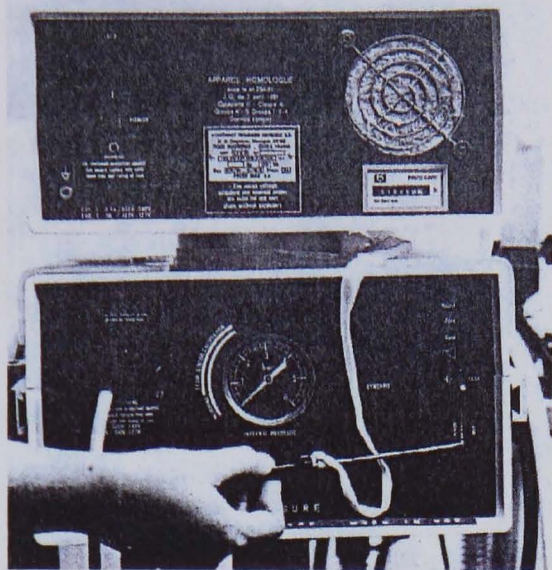


Figure 5-2. Ventilator - Assistance Technique Medicate (Source: Design, March, 1986)
(Note the attached screwdriver)

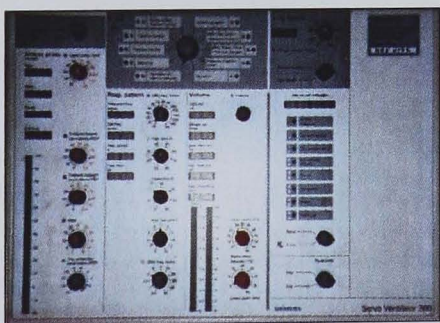
5.5.1.1.2 Study of newer Ventilators

- **Ventilator A.**

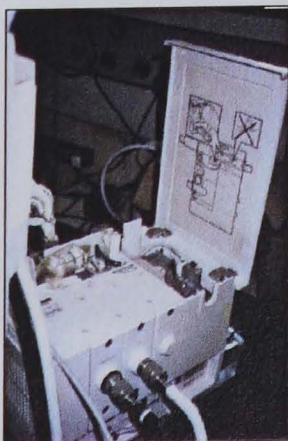
The newly installed ventilator, the Siemens Servo Ventilator 3000, was considered to have some good features. One was that the screen face can be tilted to a right angle (see Figure 5-3. A).



5-3. A



5-3. B



5-3. C



5-3. D

Figure 5-3. Ventilator - Siemens Servo Ventilator 3000

It has many different knobs and buttons but they are arranged with clear headings and a logical sequence. The control panel contains an analogue scale with the lights on it (see Figure 5-3. A, B). The screen can be taken off and put it onto another similar machine so it is not necessary to buy a separate, expensive, screen.

This new ventilator is much preferred by staff. The ventilator system has separate components such as a supply pipe for the nitric oxide (see Figure 5-3. C) and a separate free standing meter on the top.

Dr. Hamilton-Farrell (1998) stated that the ITU is buying two more newer ventilators that have a particular attachment for nitric oxide delivery (a gas used for lung failure). The newer machine has everything integral inside and each of the components on the back of the machine is in its own module that can be unscrewed and taken out if it goes wrong.

Although there are good features on the machine there is a lot to learn about its set up. However, a bad design point was highlighted. Attached to it is an ancient gantry (see Figure 5-3. D) with other switches (see Figure 5-3. A) that can work loose, and if that falls off the whole thing can just fall to the ground and drag on the patient.

- ***Ventilator B.***

An older ventilator, Purit & Bennett, has the same sort of control principle as the Siemens Servo 3000, but the difference is that it has an all push panel, in other words, it is operated by finger pushing.

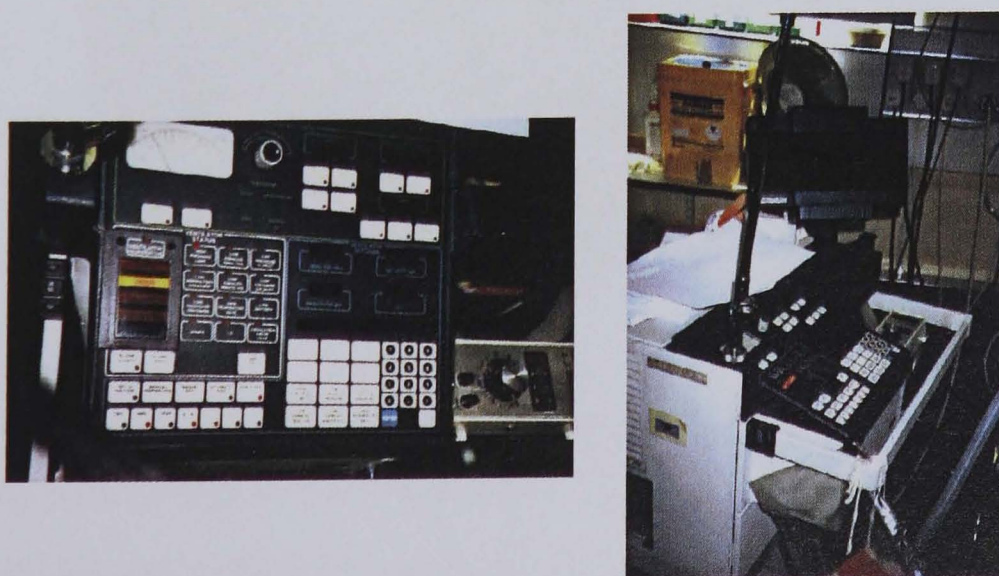


Figure 5-4. Purit & Bennett Ventilator

Although a movable screen is helpful, Hamilton-Farrell (1998) found difficulties in that there are lots of different panels close together, where a finger can drift off and press the wrong one. He believes that the set up with dials is safer and also the colours for the digital readout, rather than blue and green, would give instant visibility if they were in red.

5.5.1.2 Study of other equipment

This section discusses the other equipment installed at the ITU.

5.5.1.2.1 Other equipment installed in the past

- *Two older Digital syringe pumps*

Berman (1986) compared two digital syringe pumps, a Vickers Medica and a Maseby Medical syringe pump, as examples of badly and well designed machines, respectively. With Vickers Medica, (see Figure 5-5.A, B) a detail from its control panel shows the fault in its design. *'The illuminated area alongside the start button was being pressed to start the pump - breaking the light and potentially, the machine'* (Berman, 1986).

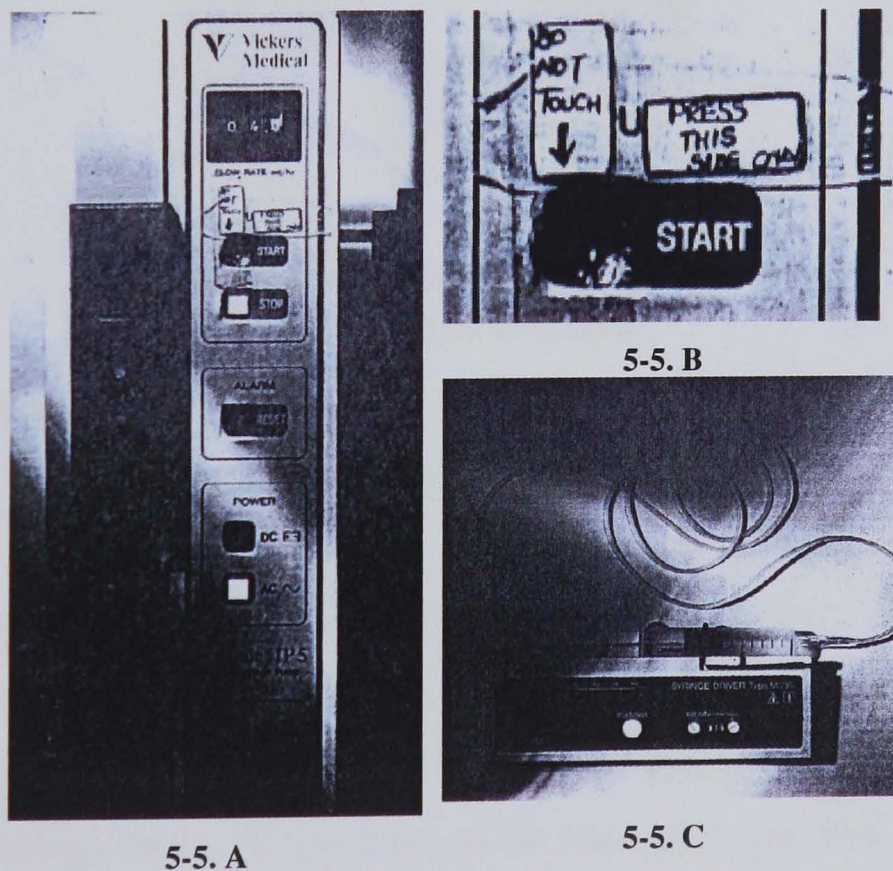


Figure 5-5. Digital syringe pumps (Source: Design, 1986)

A good example of a syringe driver was from Maseby Medical (see Figure 5-5. C). The staff at the hospital said it worked well and was easy to use generally and considered it had no faults with its design.

Hamilton-Farrell (1998) adds that with the digital syringe from Maseby the dial up system (see Figure 5-5. C) makes staff concentrate on what they are setting it to. The push button system is more prone to error. He claimed that error is a very important aspect of safety with infusion pumps, since it is the single largest cause of accidents.

5.5.1.2.2 Other equipment installed at present

This section presents other equipment installed at the ITU. Hamilton-Farrell (1998) explained his thoughts about the present equipment's good and bad points and his thoughts are fully described.

- **Defibrillator**

One good point is that, on the top of the defibrillator, the explanations panel tells users what steps to use to defibrillate. The defibrillator is only ever used in an emergency so Hamilton-Farrell said, *'even the cleverest people can forget which order to do things in... somehow I find this not quite so approachable and I can't tell you why'*.



Figure 5-6. Defibrillator

- **Dialysis machines**

Dialysis machines work on their own trolleys. *'Whatever the piece of equipment is, if you've got to put it on a separate trolley then that's a real nuisance so the stand or support that it's on is quite important'* (Hamilton-Farrell, 1998). In addition, trolleys tend to be of a standard height but Hamilton-Farrell would prefer that if it were slightly higher because a user has to bend down to control the machine. The machine itself has lots of different settings on it. Users have to be trained to use that, *'you couldn't just walk in and switch that on'*.

- **Hyperbaric oxygen unit**

Two hyperbaric oxygen units are installed at the ITU. One is a very old piece of equipment designed by Vicars in Britain, and the other is an American version of exactly the same product, built more recently, in 1996.



5-7 A1



5-7 A2



5-7 A3



5-7 B1



5-7 B2

Figure 5-7. Hyperbaric oxygen unit, 'A' made by Vicars in Britain and 'B' made by America

They both perform exactly the same function. In fact, the American version was deliberately built and designed to satisfy the same functions as the older one. Although the newer one looks rather better many patients prefer to be on the older one because there is a cooling system in the old control panel which makes it cooler for them. On the other hand, the chamber is noisier in the older model because it has gases passing through all the time, whereas the newer one has the gases just circulating. *'Ergonomically the older one is pretty terrible, the trolley itself is moveable on only four wheels whereas the trolley for the other one has five wheels and the turning circle is much much better'* (Hamilton-Farrell, 1998).

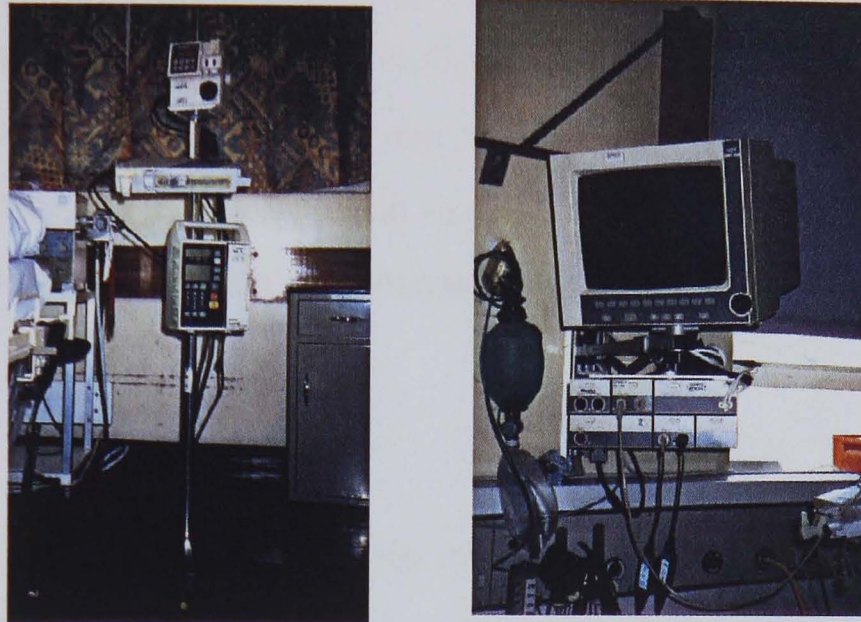
- **Monitoring systems**

Monitoring systems consist of the main measuring box with the screen in. It is a separate item from the modules servicing the various different parameters to measure.

'It happens to be a disaster, because it keeps going wrong, it just blacks out, switches itself off'. The reasons given by Hamilton-Farrell were that the equipment might be at fault or it may be that as the hospital has developed it has taken more electrical power from a mains system that was never designed for it, and occasionally it overloads.

For instance, they have discovered that occasions that cause the monitors to switch off are when somebody uses the lift in the corridor. *'It wasn't a mistake, because we bought it on the right information, but it turned out that the company is not able to service it'* (Hamilton-Farrell, 1998).

Figure 5-8. Monitoring systems



- ***Overhead lamp***

With overhead lamps the height, size and angle can be adjusted. But the tilting mechanism is not stable because it simply lifts up and the light just falls down.

- ***Oximeter***

The product are 10 years old and they are big and bulky. They do, however, have prominent red numbers on the front that users can see from anywhere, when sometimes the liquid crystal in the other similar machines can not be seen well.



Figure 5-9. Oximeter

- ***Pneumatic chute system***

A brand new piece of equipment has just been installed at the ITU. It is a simple piece of equipment, viz., a pneumatic chute to carry samples to laboratories. It is quite a big box

but it only has a very small number of settings on the front and shows pictures of how to operate it step by step. Right at the front there is a short set of instructions.

- ***Simple products***

Hamilton-Farrell (1998) claims that a chart trolley is a vital piece of medical equipment because the nurses have to recall information on this chart at all times and they can move it around. Still, these days, many intensive therapy units do have paper records. It has shelves underneath and space behind that the nurses can put things on. 'A simple thing like a chair that is actually very comfortable to sit in, adjustable height and so on, but it is quite bulky. To move it around is a real nuisance, you have to actually drag it across the floor'.

- ***Stand***

Three different machines are fixed on a drip stand that can alter its angle but it does not take much to tip it over. 'This is what I mean by all the equipment round the head of the bed. It's not good'. On the top of the stand, an infusion pump was fixed and the height was right whereas the other two pumps are fixed at the wrong height and a user has to bend right down. Furthermore, the liquid crystal screen can only be seen from a certain angle.

- ***X-ray screen***

An X-ray screen stands in a corner of the ITU because there is not enough space. The machine is very old and it does not go wrong. It is at the right height, people can stand back from it so it serves its purpose. But one light on the screen is supposed to be for staff to spotlight or highlight individual parts of an x-ray and they push it right up next to the ridge so they can not actually put the x-ray next to it.

According to Hamilton-Farrell (1998), many pieces of equipment are badly designed and this needs to be considered when designing medical equipment in the future. He added that the senior nurse at the ITU has made a successful business case saying that 'the risks of continuing as we are so great that the hospital is liable to have an accident if we continue like this. It is a terribly cluttered environment'.

Section 5.5.1.2 has shown that a lot of equipment installed in 1998 at the Whipps Cross Hospital ITU was still ill designed and still produces risks.

5.5.2 Problems in the design of new equipment

In 1986, it was reported that the medical equipment market was expanding and opportunities for designers were growing but, in fact, many medical equipment manufacturers did not employ a designer because they confused the roles of graphic and industrial designers. According to Walker (1986), Director of Investments at the Charterhouse Japhet Venture Fund, 'When I ask companies if they have a product designer they say they have a guy who does the brochure that could be used'.

There is a segment of the market involving big machines, like scanners, CAT scanners, MRI scanners, 'Philips type of products' where industrial designers are involved, but by and large only at the packaging stage, because 'they have to look sexy if you're spending £1.1/2 million on a piece of equipment' (Ramsden, 1998). Ramsden (1998) also pointed out that the problem is that design is not seen, either by designers or manufacturers, as having a contribution to make to the development of medical equipment.

In the intensive care unit, manufacturers put more and more features on because of competition, and the buyers want it but the users do not; in fact, the users want less (Ramsden, 1998).

If they can they will put it on whether you want it or not and there has to be a change in the market between there being more and more features to it being more and more cost effective. If you could prove that by a better design you would save money or be more effective then that would be a concrete argument that health-care trusts would use.

5.5.2.1 Customer opinions

Manufacturers may talk to one or two people and get an idea and say that 'We know what you want' but Hamilton-Farrell (1998) believes that '*they do not know what we want*'. The trouble is that their views may not be the same as other people's views so that makes it hard for manufacturers to satisfy everybody, and eventually they have to go ahead and build a piece of equipment.

Hamilton-Farrell (1998) believes that there is a lot more communication now than there used to be, but he thinks it is essential to have more communication with equipment manufacturers. He claimed that if medical equipment manufacturers consulted more with the people who actually use the equipment, they would find out some simple principles very quickly.

Ramsden (1998) claimed that the big problem with healthcare manufacturers is their conception or view of who the user and who the customer is. Because they are very rarely the same person, trying to get patient feedback would be very difficult for some companies. The manufacturers would normally approach the clinicians first to see if they had any problems using the equipment. Quite often the response might be that they have no problems, because if clinicians admit to having a problem using equipment then it could be perceived as a lack of skill on the clinicians part.

I had this problem looking at intensive care unit equipment. The people who buy them are normally the consultants in charge of the units so you could be very contrived about designing the product. You need to have a lot of flashing lights and things that go beep to attract the doctors and then you need to remove them all for the people who use them (Ramsden, 1998).

5.5.3 Considerations for designing new equipment

It was reported in the past that there were demands that people expect for their ideal equipment. Hanson (1986), Consultant Physician at the Whipps Cross Hospital ITU, said the ideal is equipment which is simple to use, reliable, robust, where false alarms are rare, data is easy to interpret and there is a good instruction manual. 'If they are busy, equipment needs to be robust. People slam switches when they're in a hurry'.

It was reported that equipment should be easy to clean, easy to sterilise and clean with no sharp corners, protruding legs or trailing cables. According to Berman (1986), equipment should be reliable, robust, nurse proof and doctor proof and good value: 'if it could comply with all this it certainly could be considered well designed', she added.

Although people in the past have given their opinions about ideal equipment, those issues still remain. According to Hamilton-Farrell (1998) a lot of equipment has already been changed but design changes which affect things in the future will be, first of all, safety, and secondly, visibility and simplicity of controls, because simplicity breeds safety.

He believes that the most important aspect of any design of any equipment must be safety, and since most of the equipment which is used in intensive care is electrical then electrical safety is the prime concern. So he said staff need to make sure that equipment complies with various hospital memoranda about equipment and electrical equipment.

Going beyond that, Hamilton-Farrell (1998) claims that one needs to be aware of the power source of the equipment.

Are there enough power points for the equipment that is used, and what is the means of connection between the source of power and the equipment? Are there a lot of wires necessary which may trail over the floor? And if there are not enough power points on the wall does the equipment require what is called a plug bank, or a four eight gang plug bank which is a free-standing bar of plugs which is inherently very unsafe, whether it's on the floor or hanging off the back of the equipment.

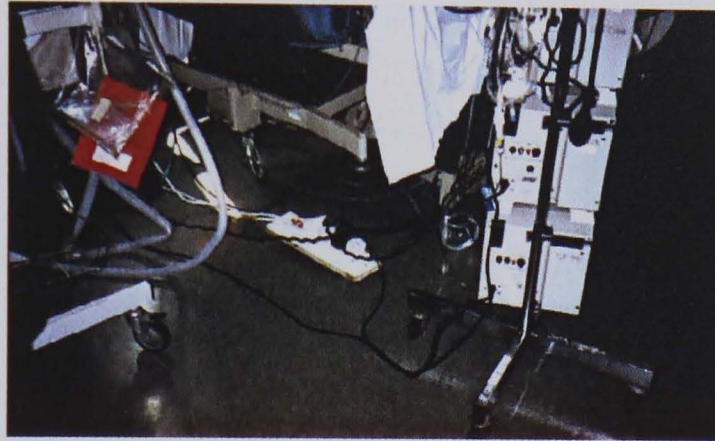


Figure 5-10. Plug bank

Hamilton-Farrell (1998) claimed that the photo shown in Figure 5-10 is an example of a 'perfect disaster situation of a plug bank'.

One needs to be sure that in the event of a sudden disconnection either the equipment is able to continue to function or there is an immediate alarm to tell that it is disconnected.

There are other issues about where any piece of equipment stands in relation to the patient. A lot of intensive care units have equipment which is stacked up around the patient's head, particularly if the patient's head is next to the wall. As a result, space between the patient's head and the wall is so cluttered up with equipment that it may be impossible to move around the back of the patient's bed, and sometimes there are many different pieces of equipment all on different functions. There may not actually be sufficient space to have all the equipment near enough to the patient, so staff may end up with a whole new set of pipes and tubes, some of which may have to come from some distance.

So the trend at the moment is towards having a supply of power and monitoring and possibly other equipment attached to something that comes out of the ceiling, like a boom, and the Whipps Cross ITU will have one of them. There are several which have already been installed at ITU's in other hospitals.

It does have design implications for the building because if you have everything coming out of the ceiling on a boom that carries a lot of weight you have to be sure that the ceiling is strong enough to take it. But having lifted all the kit away from the floor and having removed all the trailing wires and pipes coming from long distances, then it makes everything much safer. You can get round the back of the patient's head easily (Hamilton-Farrell, 1998).

Ramsden (1998) claimed that there are user issues which are a key element that need to be addressed.

Accurately identifying who the user is and what their requirements are involves a lot more feedback to the patient because you want reassurance and a lot of the healthcare equipment does not give you any reassurance or feedback with doing anything.

According to Ramsden (1998), the particular problem in designing medical equipment is making something which works differently for different users:

The way people use the products varies. A toaster just makes toast for someone, but in medicine there is a patient, the technician, the nurse, the doctor and the visitors, who will all be facing the equipment. With new technology you can start to design in such a way that a machine's behaviour varies according to the user. You can have different displays, showing greater or lesser details, depending on who's looking at the screen.

Many considerations need to be addressed for the designing of medical equipment. The issues discussed in this section will produce the criteria for the designing of medical equipment. These will be compared with home-based health-care equipment in Chapter 11.

5.5.4 Overall problems in using equipment

Although the equipment used at Whipps Cross ITU has been virtually changed, some problems still remain, especially with environmentally and badly designed older machines which are still in use. Even newer machines have problems in use, although most are also thought to have good points (see Table 5-7).

As presented in Table 5-7, there are good and bad points to the products which are designed at present and past time. This survey shows that a lot of equipment installed at the Whipps Cross ITU is ill designed and produces risks.

[illegible]

Table 5-7. Product problems (✖) & good point (●) at Whipp's Cross ITU

Although the medical equipment market is expanding and opportunities for designers are growing, many medical equipment manufacturers do not employ a designer because they confuse the roles of industrial designers. There are industrial designers involved, but by and large only at the packaging stage. The problem is that design is not seen, either by designers or manufacturers, as having a contribution to make to the development of medical equipment.

The problem with healthcare manufacturers is their conception or view of who the user and who the customer is. Because these two, the user and the customer, are very rarely the same person, trying to get patient feedback is therefore considered to be very difficult for some companies.

The trouble is that manufacturers' views may not be the same as other people's views so that makes it hard for manufacturers to satisfy everybody, and eventually they have to go ahead and build a piece of equipment.

There is a lot more communication now than there used to be, but it would be better to have more communication with equipment manufacturers. If medical equipment manufacturers consulted more with the people who actually use the equipment, they would find out some simple principles very quickly.

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Chapter 6

Questionnaire Survey with Manufacturers

CHAPTER 6. QUESTIONNAIRE SURVEY WITH MANUFACTURERS

6.1 Introduction

This chapter presents the findings of the manufacturers' survey. The questionnaire design focused on companies' product manufacture and design. The survey aimed to gather basic information from the industry in order to ascertain important features of the design process that they use. It tried to find out if and how they convert users' opinions into specifications for new product design.

This chapter starts with a general discussion of the manufacturer questionnaire survey findings. Section 6.3 summarises the types of equipment used in this survey. Section 6.4 presents manufacturers' questionnaire analysis.

6.2 Results of the manufacturer survey

This manufacturer survey was conducted using a questionnaire in combination with interview. The results of the interviews are presented in Chapter 7. The respondents were asked both simple optioned questions and also open-ended questions.

The answers to the open ended questions were subjected to content analysis and concepts based on groups of responses and are recorded as discussed in Chapter 3.

This survey involved 22 manufacturers (see Table 6-1). These companies manufacture and design their equipment using in-house design team, overseas headquarters' design team or design consultants. The answers to the questions were reassembled into related groups and analysed in order to achieve the following six objectives.

To identify: 1. Medical treatment & equipment types manufactured.

2. Opinions about effectiveness of home treatment equipment.

3. Practical use of the design department and make up.

4. Opinions about new product development.

5. How users' opinions are obtained and converted.

6. Opinions about home-based health-care market and possible areas for expansion

Table 6-1. Manufacturers & respondents

Manufacturers	Name	Position	Question naire	Inter view
1. A and M Hearing Ltd.	Mr. Gibbs	Manager	Yes	Yes
2. Arjo Ltd.	Mr. Somerton	Managing Director	Yes	Yes
3. Baxter Healthcare Ltd.	Ms. G. Stansfield	APD Manager	Yes	Yes
4. Boehringer Mannheim UK Ltd.	Mr. T. Glanfield	Technical Specialist	Yes	No
5. Clement Clarke International Ltd.	Mr. P. Guy	Product Manager	Yes	Yes
6. Drager Medical Ltd.	Mr. N. Pattinson	Manager	Yes	Yes
7. Edale Instruments (Cambridge)	Mr. A. Hodgson	Director	Yes	Yes
8. EMS (Electro Medical Supplies) Ltd.	Mr. D. Wilton	Technical Director	Yes	Yes
9. Gambro	Mr. P. Middleton	Manager	Yes	Yes
10. Gimson Stairlifts Ltd.	Mr. Blackburn	Manager	Yes	Yes
11. Huntleigh Nesbit Evans (HNE) Technology plc Group	Dr. S. Cook	Group Technical Director	Yes	Yes
12. Johnson & Johnson Medical Ltd.	Mr. S. Atkinson	Marketing Manager	Yes	No
13. Medelec Ltd.	Dr. V. Mifsud	Technical Director	Yes	No
14. Medex Medical Ltd.	Ms. L. Fountaine	Senior Representative	Yes	Yes
15. Medic-Aid Ltd.	Ms. K. Dexter	Product Manager	Yes	No
16. Medi Sense Inc.	Dr. Sanghera	Technical Director	Yes	No
17. Novamedix Ltd.	Mr. I. Brown	Marketing Director	Yes	Yes
18. Oxford Instruments Ltd.	Ms. P. Hobday	Manager	Yes	Yes
19. Philips Electronics Ltd. (DAP Dept.)	Mr. D. Stevens	Product Manager	Yes	No
20. P.K. Morgan Ltd.	Mr. K. Hogben	Sales Manager	Yes	No
21. Pneu PAC Ltd.	Dr. N. Jones	Technical Director	Yes	No
22. Smith Industries Medical Systems Ltd.	Dr. E. Yoxen	Director	Yes	No

The following section is preceded by brief explanations of the nature of the equipment.

6.3 Types of equipment manufactured by the companies taking part in this survey

Equipment was categorised into 7 different groups.

1. Respiratory equipment	2. Hearing aid equipment
3. Hygiene and transferring equipment	4. Therapeutic equipment
5. Dialysis equipment	6. Monitoring equipment
7. Ambulatory drug delivery equipment	

The different products revealed by the survey are listed below under the seven category headings.

6.3.1 Respiratory equipment

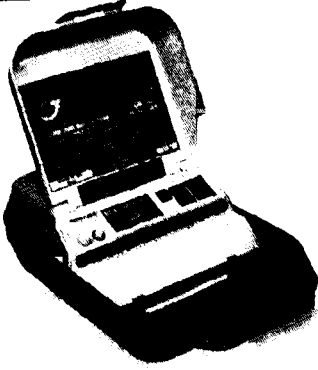


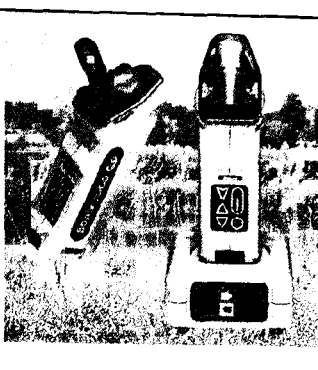

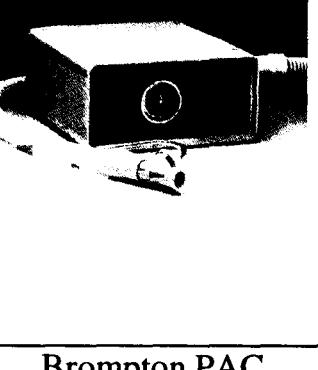
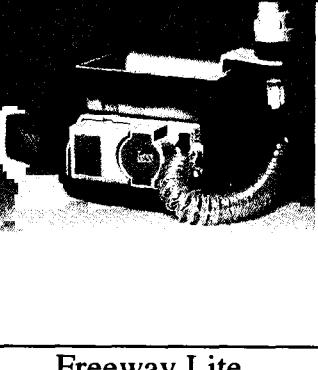
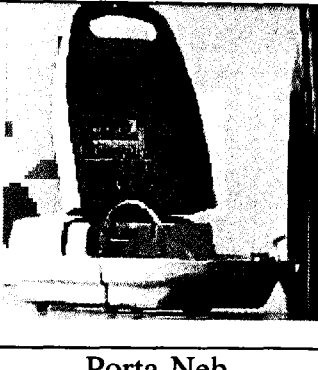
			
AC 2000	EconoNeb	World Traveller	Sonix 2000
			
RespiCare	Brompton PAC	Freeway Lite	Porta-Neb

Figure 6-1. Respiratory equipment

Clement Clarke International Ltd. produces the Medix *AC 2000*, *EconoNeb*, *World Traveller* and *Sonix 2000* which are described in Section 4.6.1.3 (see pp. 141-142). Drager Medical Ltd.'s *RespiCare* is for home use ventilation. Pneu PAC Ltd. produces the *Brompton PAC*, an assist-controller ventilator for home and hospital. Medic-Aid Ltd.'s *Freeway Lite* is a portable nebuliser compressor and *Porta-Neb* is designed for home use.

6.3.2 Hearing aid equipment

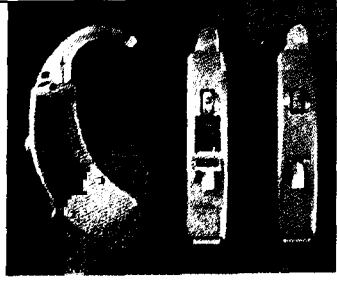

	
AM510	Pro series

Figure 6-2. Hearing aid equipment

A&M Hearing Ltd. manufactures the *AM510*, a medium sized hearing instrument and the *Pro series*, a programmable hearing instrument control circuitry system.

6.3.3 Hygiene and transferring equipment

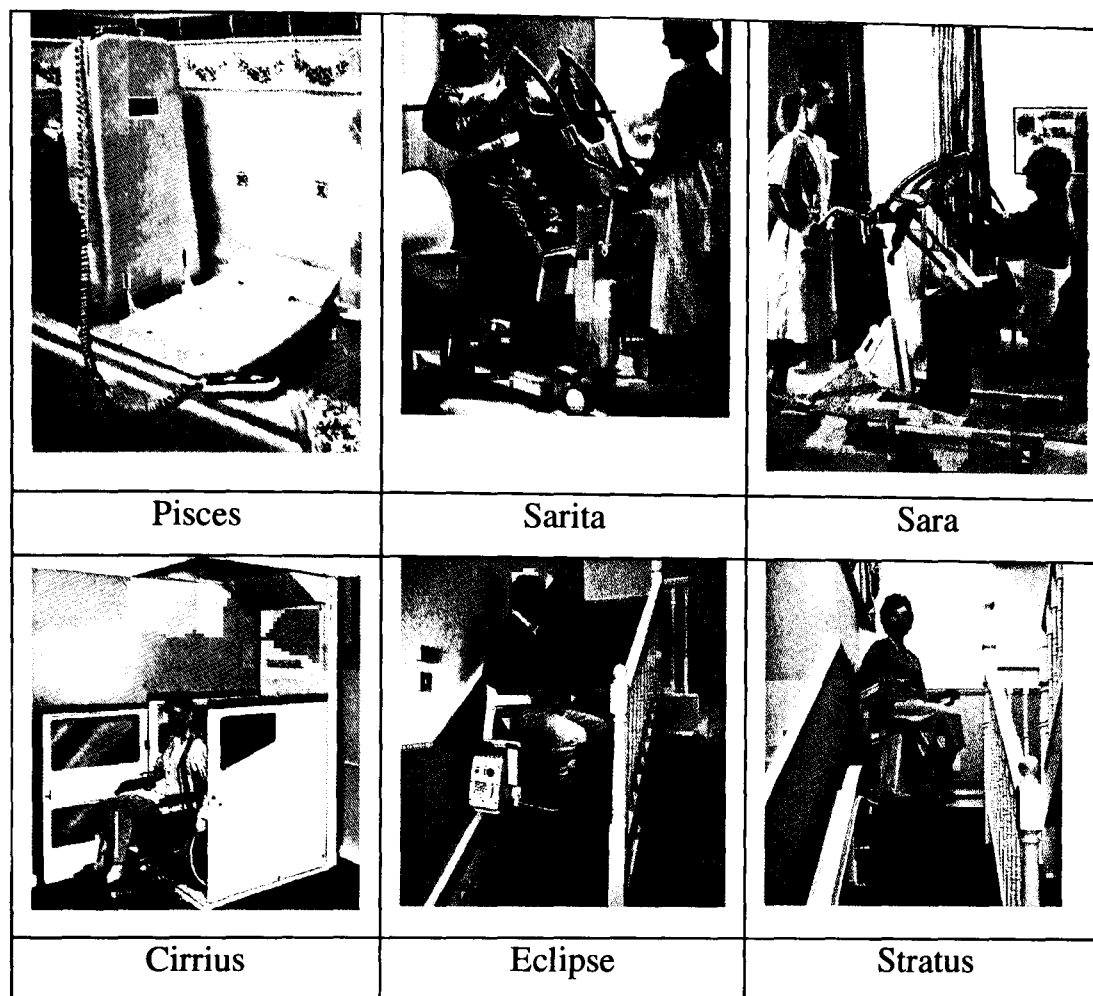


Figure 6-3. Hygiene and transferring equipment

Huntleigh Kinetics's *Pisces* is a folding bathlifter. Arjo Ltd.'s *Sarita* and *Sara* are patient operated aids for standing, raising and transferring. Gimson Stairlifts Ltd. manufactures *Cirrius*, a domestic lift and the *Eclipse* and *Stratus* which are stairlifts.

6.3.4 Therapeutic equipment

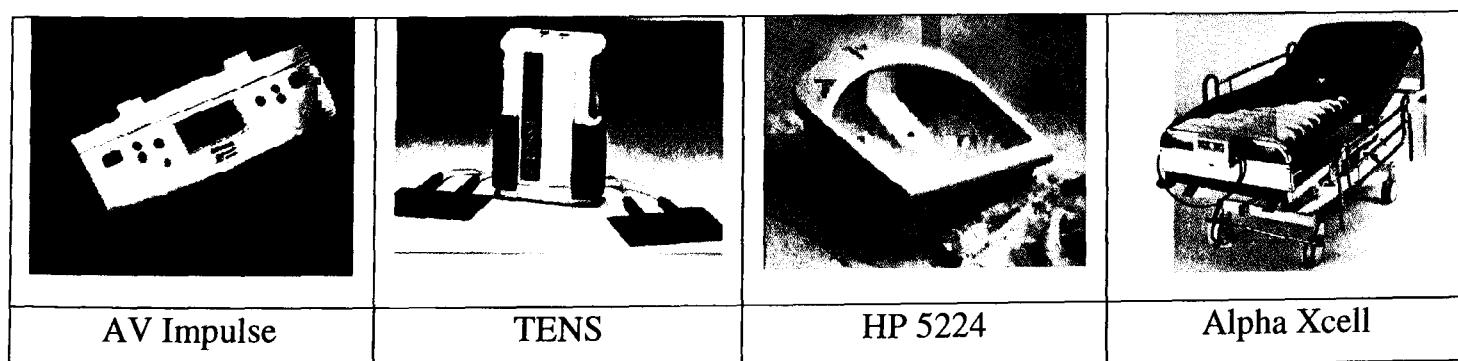


Figure 6-4. Therapeutic equipment

Novamedix Ltd. manufactures the *AV Impulse* system which enhances blood circulation and the EMS *Tens* which uses tens therapy which is programmed in a CPU (central processing unit). Philips Electronics Ltd. (DAP Dept.) manufactures the *HP 5224*, with a massaging action which is claimed to improve blood circulation. Huntleigh Healthcare's *Alpha Xcell* is an active pressure relieving mattress overlay system.

6.3.5 Dialysis equipment

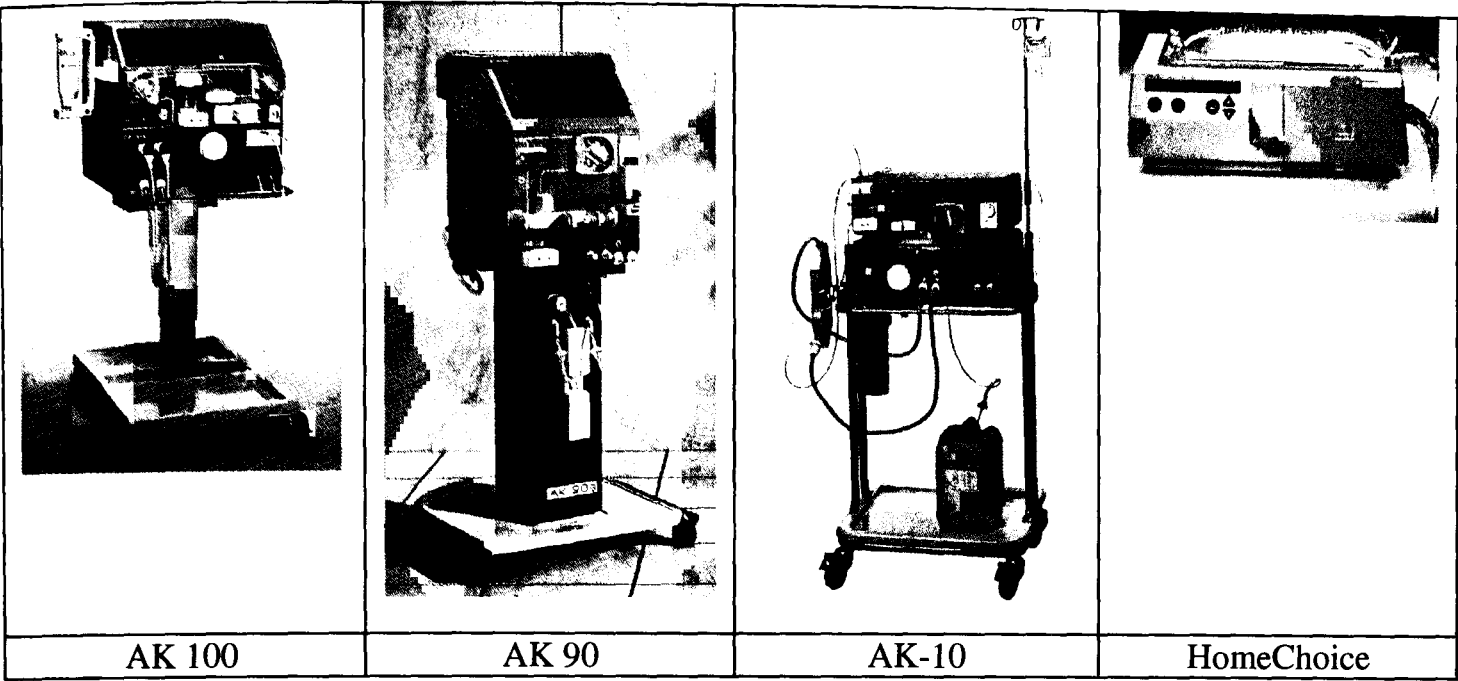


Figure 6-5. Dialysis equipment

Gambro's *AK 100*, *AK 90* and *AK-10* are haemo dialysis equipment (see p. 82). Baxter Healthcare Ltd.'s *HomeChoice* is a peritoneal dialysis product (see p. 101).

6.3.6 Monitoring equipment

6.3.6.1 Digital monitoring equipment

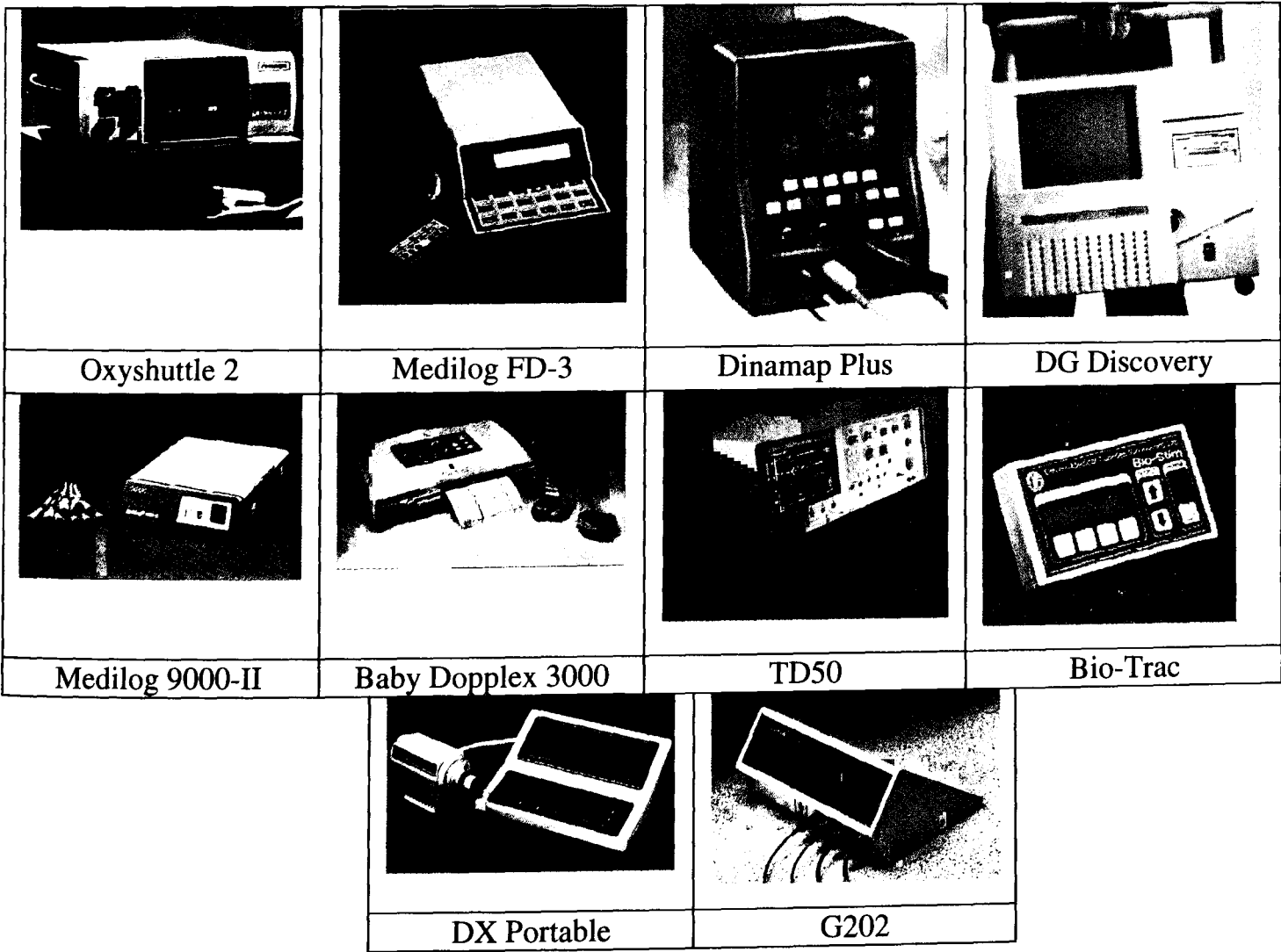


Figure 6-6. Digital monitoring equipment

Oxford Instruments Ltd.' *Medilog FD-3* is a digital ECG (electrocardiography) recorder and *Medilog 9000-II* is an EEG (electroencephalography) ambulatory recorder. Johnson & Johnson Medical Ltd.'s *Oxyshuttle 2* is an oxygen saturation measurement system and *Dinamap Plus* is a vital signs monitor which measures diastolic blood pressure, heart rate and temperature. Medelec Ltd. manufactures the *DG Discovery*, a portable EEG system for recording and diagnostic use and the *TD50* which is a portable EMG (electromyography). Huntleigh Diagnostics's *Baby Dopplex 3000* is a fetal monitor for recording fetal heart rates. EMS Ltd.'s *Bio-Trac* is a single channel biofeedback EMG (electromyography) unit. P.K. Morgan Ltd.'s *DX Portable* is a portable spirometry system. Edale Instruments' *G202* is a digital medical thermometer.

6.3.6.2 Diabetes monitoring equipment

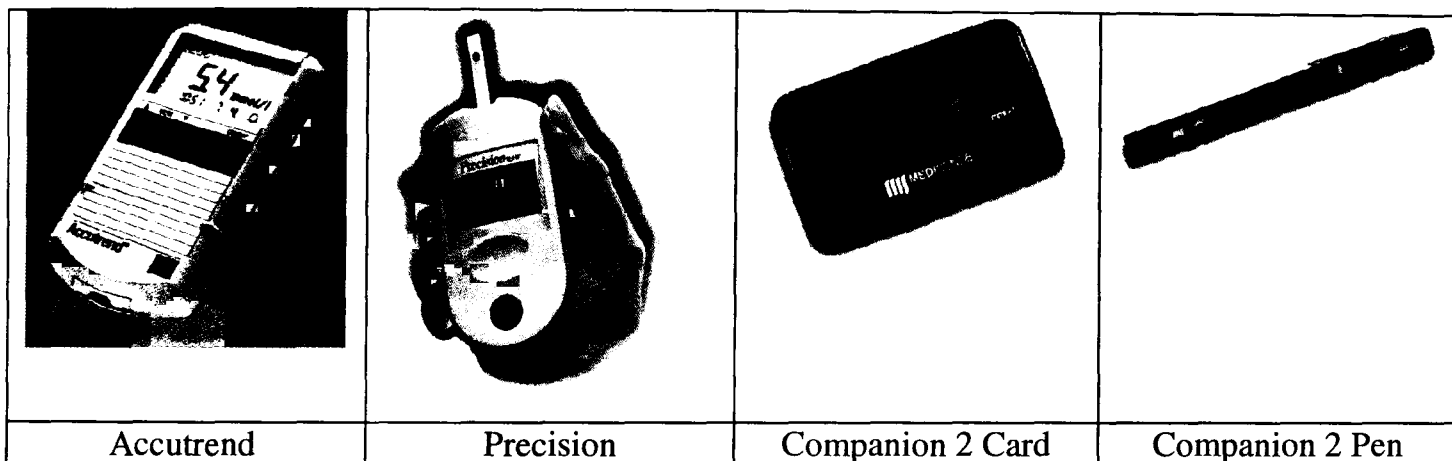


Figure 6-7. Diabetes monitoring equipment

Boehringer Mannheim UK Ltd.'s *Accutrend* is a blood glucose monitoring device. MediSense Inc. manufactures *Precision* a hand-held blood glucose monitor and *Companion 2 Card* and *Companion 2 Pen* which are blood glucose sensors using biosensor technology.

6.3.7 Ambulatory drug delivery equipment

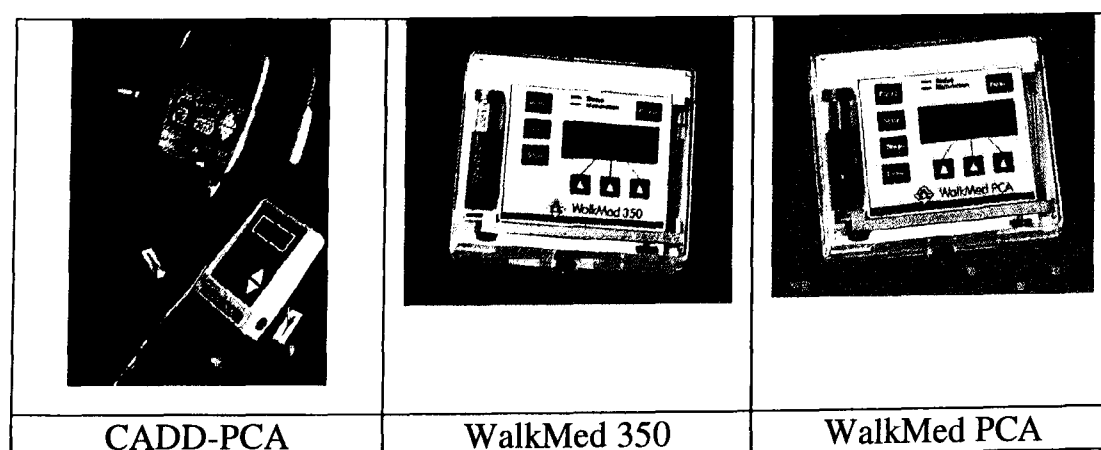


Figure 6-8. Ambulatory drug delivery equipment

Smith Industries Medical Systems Ltd. **CADD-PCA** is a range of programmable ambulatory drug delivery pumps. Medex Medical Ltd.'s **WalkMed 350** and **WalkMed PCA** are ambulatory infusion pumps for continuous delivery.

The following sections provide the results of the questionnaire.

6.4 Manufacturers' questionnaire survey

Objective 1. To identify medical treatment & equipment types manufactured.

1. What types of medical equipment / health-care equipment do you supply for professional use?

Total respondents were twenty-two manufacturers and the types of equipment categorised by their own answer to the question.

Company	Equipment types	Company	Equipment types
1. A and M Hearing Ltd.	Hearing aids products	2. Arjo Ltd.	Patient handling equipment
3. Baxter Healthcare Ltd.	Peritoneal dialysis equipment	4. Boehringer Mannheim UK Ltd.	Blood glucose monitoring equipment
5. Clement Clarke International Ltd.	Respiratory equipment	6. Drager Medical Ltd.	Respiratory equipment
7. Edale Instruments	Digital thermometers	8. EMS Ltd.	Electro therapy equipment
9. Gambro	Dialysis equipment	10. Gimson Stairlifts Ltd.	Domestic lifts
11. HNE Technology plc Group	Diagnostic and patient handling equipment	12. Johnson & Johnson Medical Lt.	Patient monitoring equipment
13. Medelec Ltd.	Neuro-diagnostic equipment Digital EEG equipment	14. Medex Medical Ltd.	Infusion therapy equipment
15. Medic-Aid Ltd.	Aerosol drug delivery systems	16. Medi Sense Inc.	Blood glucose testing systems
17. Novamedix Ltd.	Blood circulation enhancement equipment	18. Oxford Instruments Ltd.	Ambulatory patients monitoring equipment
19. Philips Electronics Ltd. (DAP Dept.)	Diagnostic imaging equipment	20. P.K.Morgan Ltd.	Respiratory clinical diagnostic equipment
21. Pneu PAC Ltd.	Ventilators and anaesthesia equipment	22. Smith Industries Medical Systems Ltd.	Patient controlled analgesia, tracheotomy tubes, urology, ostomy, etc. products

Many of above companies manufacture various types of equipment but this survey concentrates on home environment associated equipment. The equipment types described above are the respondents' own explanation.

Equipment types	Company
Respiratory equipment	<ol style="list-style-type: none"> 1. Clement Clarke International Ltd. 2. Drager Medical Ltd. 3. Pneu PAC Ltd. 4. Medic-Aid Ltd.
Hearing aid equipment	<ol style="list-style-type: none"> 1. A &M Hearing Ltd.
Hygiene and transferring equipment	<ol style="list-style-type: none"> 1. Huntleigh Kinetics 2. Arjo Ltd. 3. Gimson Stairlifts Ltd.
Therapeutics equipment	<ol style="list-style-type: none"> 1. Novamedix Ltd. 2. EMS Ltd. 3. Philips Electronics Ltd. (DAP Dept.) 4. Huntleigh Healthcare
Dialysis equipment	<ol style="list-style-type: none"> 1. Gambro 2. Baxter Healthcare Ltd.
Monitoring equipment	<ol style="list-style-type: none"> 1. Oxford Instruments Ltd. 2. Johnson & Johnson Medical Ltd. 3. Medelec Ltd. 4. Huntleigh Diagnostic 5. EMS Ltd. 6. P.K. Morgan Ltd. 7. Edale Instruments 8. Boehringer Mannheim UK Ltd. 9. MediSense Inc.
Ambulatory drug delivery equipment	<ol style="list-style-type: none"> 1. Smith Industries Medical Systems Ltd. 2. Medex Medical Ltd.

22 companies' equipment categorised into 7 types.

Objective 2. To identify opinions about effectiveness of home treatment equipment.

2. Does your organisation supply hospital equipment and home use equipment, nominally for the same treatment?
3. If yes to 2. Please give equipment names & types & please supply technical sales leaflets (if available).
4. Does home treatment equipment effectively reach more patients than hospital treatments of same or similar types?

Company	Products	Y/N	Company	Products	Y/N
1. A and M Hearing Ltd.	AM510 Pro Series	Y Y	2. Arjo Ltd.	Sara Sarita	Y Y
3. Baxter Healthcare Ltd.	HomeChoice	Y	4. Boehringer Mannheim UK Ltd.	Accutrend	Y
5. Clement Clarke International Ltd.	Sonic 2000 AC2000 EconoNeb World Traveller	Y Y Y Y	6. Drager Medical Ltd.	Respicare	Y
7. Edale Instruments	G202	Y	8. EMS Ltd.	TENS Bio-Trac	Y N
9. Gambro	AK-10 AK 90 AK 100	Y Y Y	10. Gimson Stairlifts Ltd.	Eclipse Stratus Cirrius	Y Y Y
11. HNE Technology plc Group	Alpha Xcell Baby Dopplex 3000 Pisces	Y Y Y	12. Johnson & Johnson Medical Ltd.	Dinamap Plus Oxyshuttle 2	N N
13. Medelec Ltd.	DG Discovery TD50	N N	14. Medex Medical Ltd.	Walkmed PCA Walkmed 350	Y Y
15. Medic-Aid Ltd.	Porta-Neb Freeway Lite	Y Y	16. Medi Sense Inc.	Precision Companion 2 Card Companion 2 Pen	Y Y Y
17. Novamedix Ltd.	AV Impulse	Y	18. Oxford Instruments Ltd.	Medilog FD-3 Medilog 9000-II	N N
19. Philips Electronics Ltd. (DAP Dept)	HP 5224	Y	20. P.K. Morgan Ltd.	DX Portable	N
21. Pneu PAC Ltd.	Brompton PAC	Y	22. Smith Industries Medical Systems Ltd.	CADD-PCA	Y

22 companies supplied 41 home use products. The respondents answered that 78% of products effectively reach more patients than hospital treatments of same or similar types; the minority 22% was electro monitoring equipment, most of which is mainly used in hospitals with a small but expanding home care market.

Objective 3. To identify practical use of the design department and make up.

- 7. Do you have your own design team?
- 8. If yes to 7. What is its professional make up?
- 9. If no to 8. Who designs the equipment you produce?

The following options were available to tick appropriate answers to question 8.

- industrial designer
- technician
- production
- engineer
- ergonomist
- etc._____.

Question 9 was open-ended.

Design team	Number of companies	
In house design team	16	
HQ design team	4	6
Design consultants	2	

16 companies had in-house design teams but 6 companies did not.

Professional make up	Number	Professional make up	Number
Industrial designer	5	Marketing	2
Technician	9	Clinical	1
Production	16	Quality	2
Engineer	16	Soft ware	2
Ergonomist	2	Hard ware	1

Out of 56 people working in in-house design teams, only 5 were industrial designers, a very small proportion. The above table shows that design departments are driven by strong production, engineering and technician involvement.

Objective 4. To identify about new product development.

10. Have you introduced any new products or product modifications during the last 2 years?

11. If yes to 10. How many?

12. Do you produce your own new product design briefs?

Company	Number	Y/N	Company	Number	Y/N
1. A and M Hearing Ltd.	7-8	Y	2. Arjo Ltd.	3-4	Y
3. Baxter Healthcare Ltd.	5	Y	4. Boehringer Mannheim UK Ltd.	5	N
5. Clement Clarke International Ltd.	2-3	Y	6. Drager Medical Ltd.	6	Y
7. Edale Instruments	6	Y	8. EMS Ltd.	1-2	Y
9. Gambro	2	Y	10. Gimson Stairlifts Ltd.	2	Y
11. HNE Technology plc Group	4-5	Y	12. Johnson & Johnson Medical Ltd.	3-4	Y
13. Medelec Ltd.	4	Y	14. Medex Medical Ltd.	2-3	Y
15. Medic-Aid Ltd.	2	Y	16. Medi Sense Inc.	2	Y
17. Novamedix Ltd.	2	Y	18. Oxford Instruments Ltd.	8	Y
19. Philips Electronics Ltd. (DAP Dept.)	5	N	20. P.K. Morgan Ltd.	1-2	Y
21. Pneu PAC Ltd.	1-2	Y	22. Smith Industries Medical Systems Ltd.	4-5	Y

All the companies introduced 3 to 4 new products on average each year. This data covers not only home healthcare products but also other products which they manufacture. Only two companies did not produce new product design briefs, one reason being that they have design headquarters abroad.

Objective 5. To identify how users' opinions are obtained and converted.

13. Do users' opinions feature in the product change brief?
14. If yes to 13. How do you obtain their opinions?

The following options were available to tick appropriate answers to question 14.

- customer enquires
- sales department
- questionnaires
- customer homes
- etc._____.

Customer opinions from	Number	Customer opinions from	Number
Customer enquires	18	Focus group	2
Sales department	18	Panel meetings	1
Questionnaires	8	Literature	1
Customer homes	8	Discussions with medical staff	1
Market research	5		

A total of 62 answers were given. All the companies claim to have featured users' opinions in their product change briefs.

Objective 6. To identify opinions about home-based health-care market and possible areas for expansion.

5. Do you think there is scope for more home care treatments with suitable equipment and back up?
6. If yes to 5. Can you suggest any examples?
15. Do you think the total market for home-based health-care equipment is expanding?

Company	Examples
Medex Medical Ltd.	Extension to current application of pumps for long term home support therapies
Baxter Healthcare Ltd. Gambro	Home-dialysis
Boehringer Mannheim UK Ltd.	Coagulation therapy monitoring, cholesterol/ triglycerioes monitoring long term ventilation
Drager Medical Ltd.	Long term ventilation or respiratory support
EMS Ltd.	pain relief (stircriotons), Biofeedisach (EMG) Continue treatment
HNE Technology plc Ltd.	Better, more cost effective samples
Johnson & Johnson Medical Ltd.	Blood pressure cuffs(easy to use, either in the home or in hospitals)
Medelec Ltd.	In our field, future extensions to stimulate/ control muscles in severe injuries, but market is small. EEG recording at home(ambulatory) is already starting
Medi Sense Inc.	Glucose, Renal dialysis care, Sports medicine
Novamedix Ltd	Treatment of most chronic ulcers
Oxford Instruments Ltd.	Most conditions currently conducted in hospitals
Pneu PAC Ltd	Ventilation, O2 therapy

The above table shows that manufactures think the current market can be expanded into other areas. Extension of current application of products will make the home health-care market more feasible. 20 out of 22 companies think that the home-based health-care market is expanding and only 2 companies were less sure about this area.

6.5. Summary

Equipment was categorised into 7 different groups: ambulatory drug delivery equipment, dialysis equipment, monitoring equipment, hygiene & transferring equipment, therapeutic equipment, respiratory equipment, and hearing aids.

It was identified that design departments are driven by strong production, engineering and technician involvement. Only a small number of manufacturers stated that industrial designers were employed in the design department.

All the manufacturers claimed to have featured users' opinions in their product change briefs. The majority of customer opinions are from customer enquires and via the sales department.

Further information from manufacturers was obtained by interview and the results are given in the next chapter.

Chapter 7

Interviews with Manufacturers

CHAPTER 7. INTERVIEWS WITH MANUFACTURERS

7.1 Introduction

This chapter gives the results of interviews with manufacturers of home-based health-care equipment. The aim of the interviews was to identify how manufacturers convert users’ opinions into design specifications and to identify deficiencies in the design process of home-based health-care equipment.

This chapter starts with a discussion about the study of manufacturers and how they design a product. Section 7.3 summarises the three different types of manufacturers. Section 7.4 gives a brief description of types of standards organisations and types of approvals. Section 7.5 presents how manufacturers convert users’ opinions into the design specification. Section 7.6 discusses design procedures in new product development and the place of design in organisations. Section 7.6 discusses current market trends and future expectations. The final section of this chapter presents the overall findings of the manufacturer interviews.

7.2 The study of manufacturers and design

The study of manufacturers was based on interviews and company literature. The equipment was manufactured and designed by companies using in-house design teams, overseas headquarters design teams or design consultants.

These interviews involved 13 manufacturers and 1 company surveyed by post. A total of 14 places and 24 people were involved in this survey. Interviewees were generally a senior manager or technical/managing director (see Table 7-1).

Table 7-1. Manufacturers and respondents

Manufacturers	Name	Position	Interview
1. A and M Hearing Ltd.	Mr. Gibbs	Manager	Yes
	Mr. R. Lintern	Mechanical Design Engineer	Yes
2. Arjo Ltd.	Mr. Somerton	Managing Director	Yes
3. Baxter Healthcare Ltd.	Ms. G. Stansfield	APD Manager	Yes
4. Clement Clarke International Ltd.	Mr. P. Guy	Product Manager	Yes
5. Drager Medical Ltd.	Mr. N. Pattinson	Manager	Yes
6. Edale Instruments	Mr. A. Hodgson	Director	Yes

7.	Electro Medical Supplies (EMS) Ltd.		Mr. D. Wilton	Technical Director	Yes
8.	Gimson Stairlifts Ltd.		Mr. Blackburn	Manager	Yes
9.	Gambro Ltd.		Mr. G. Anderson	Marketing Manager	Yes
10.	Huntleigh Nesbit Evans (HNE) Technology plc Group	HNE Technology plc Group	Dr. S. Cook, Mr. J. Harding Mr. D. Bentley	Group Technical Director Group Industrial Designer Group Regulatory Manager	Yes Yes Yes
		Huntleigh Healthcare in <i>Luton</i>	Mr. C. Daughtery Mr. M. Henderson Mr. D. Kemp	Technical Manager Programme Manager Project Manager	Yes Yes Yes
		Huntleigh Kinetics in <i>Liverpool</i>	Mr. L. Brooks Mr. S. Morrissey Mr. P. Westcott	Operations Manager Marketing Manager Technical Manager	Yes Yes Yes
		Huntleigh Diagnostic in <i>Cardiff</i>	Mr. G. Baily	Technical Manager	Yes
11.	Medex Medical Ltd.		Ms. L. Fountaine	Senior Representative	Yes
12.	Medic-Aid Ltd.		Ms. K. Dexter	Product Manager	By post
13.	Novamedix Ltd.		Mr. I. Brown	Sales & Marketing Director	Yes
14.	Oxford Instruments Ltd.		Ms. P. Hobday	Director of Strategic Planning	Yes
			Ms. H. Chia	Product Manager	Yes

7.3 Three different types of manufacturers

Products were designed in three different ways, by in-house design teams, designed by headquarters overseas or using design consultants.

Table 7-2. Product design: types of manufacturers

Type	Product design by	Manufacturer
Type I	In-house design team	Arjo Ltd Clement Clarke International Ltd. EMS Ltd. Huntleigh Healthcare in Luton Huntleigh Kinetics in Liverpool Huntleigh Diagnostic in Cardiff Medic-Aid Ltd.
	In-house design team associated with overseas headquarters	A and M Hearing Ltd. Gimson Stairlifts Ltd.
Type II	Overseas headquarters	Baxter Healthcare Ltd. Drager Medical Ltd. Gambro in Lund, Sweden Medex Medical Ltd.
Type III	Design consultants associated with in-house design team	Oxford Instruments Ltd.
	Design consultants	Edale Instruments Novamedix Ltd.

Type I manufacturer can be divided into two groups, using an in house design team and an in-house design team associated with overseas headquarters. Type II organisation is the UK sales arm of an overseas manufacturer. Type III manufacturer can also be divided into two groups, those that rely on design consultants and those that combine an in-house design team with the use of design consultants.

7.4 A brief description of the types of standards organisations

Every country has its own set of legal requirements but the two biggest markets are Europe and the United States. As manufacturers of medical devices, companies have to satisfy all legal requirements for the European Union and the United States, as appropriate.

Regulations have changed with increasing frequency during the last decade. This has caused tremendous impact on design procedures to the manufacturers (Hobday, Oxford Instruments Ltd., 1997; Henderson, Huntleigh Healthcare, 1997). Bentley (1998) claims that in America the FDA (Food and Drug Administration) have had regulations since 1974 and people are quite used to it, but in the European Union the MDD (Medical Devices Directive) is quite new, and that is why there is such emphasis on it. Most of the interviewees mentioned the growing importance of regulations and standards including ISO 9000, CE Mark, GMP, 510K, etc. This section, therefore, provides a brief description of types of standards organisations and approvals for Europe and America.

7.4.1 Legislation -The European Union Medical Devices Directive

The new EU Medical Devices Directive 94/42/EEC came into effect on 1 January 1995. This legislation, which took full effect on 14 June 1998, concerns the CE Mark, a method for harmonising device approval within the community. The Directive, also called a competent body or a notified body, assesses the quality system at the factory or the product in terms of safety testing, electrical safety or mechanical safety, etc. (Bentley, HNE Technology plc Group, 1998).

Classification

The Directive sets down a framework of requirements and is based on assessing effectively the type of risk that the product presents to the patient and the carer involved with their treatment. The main point is dependent on the classification that each product has to meet the different requirements. The products are classified into four different types; Class I, Class IIa, Class IIb and Class III. Class I represents the lowest risk products, generally those which do not make contact with the patient. Class III is the highest risk, products which are invasive and used on the heart, lungs or central nervous system. The Micro Pump for example, it is not invasive, not for channelling or storing blood, not modifying the biological or chemical composition of blood etc. so it ends up

with a Class I. Once the product is classified, the Directive suggests what to do. For example, if it is a Class 3 product then a notified body takes the products and examines them to see whether it is safe and meets the requirements or not, along with a verification procedure (Bentley, 1998, see Appendix 4).

7.4.1.1 CE (European Conformity) mark

The CE mark is the official marking required by the European Community for all electric and electronic equipment that will be sold, or put into service for the first time, anywhere in the European Community. It proves to the buyer or user that a product fulfils all essential safety and environmental requirements as they are laid down in the European Directives. The CE markings directive (93/68/EEC) was adopted on 07-22-1993, and provided requirement standards for a range of electric and electric equipment (Schnoll, 1997), examples of which can be seen in Table 7-3.

Table 7-3. Directives (Source :Schnoll, 1977)

Directive	No.	Mandatory Since
Telecommunications	(91/263/EEC)	1-1-1992
Terminal equipment Machine Safety		1-1-1995
Electromagnetic Compatibility (EMC)	(89/336/EEC)	1-1-1996
Electrical Safety (Low Voltage Directive)	(73/23/EEC)	1-1-1997

7.4.1.2 ISO (International Organisation for Standardisation)

CE marking is a product certification which is a requirement for products in EC countries. An ISO 9000 Quality System is a requirement for suppliers and manufacturers of CE-marked products. In fact, ISO9000 is a quality system which is followed by the company. It regards quality procedures that are concerned with manufacturing and with all the other functions of the company. ISO9001 deals with the quality of the whole company and ISO9002 relates only to manufacturing quality. The ISO is a worldwide federation of national standards bodies, from some 90 countries. It promotes the development of standardisation and related activities to facilitate the international exchange of goods and services, and develop intellectual, scientific, technological and economic co-operation (ISO, 1998).

Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines, or definitions of characteristics, to

ensure that materials, products, processes and services are fit for their purpose. For example, the format of credit cards, phone cards, and 'smart' cards that have become commonplace is derived from an ISO International Standard. Adhering to the standard, which defines such features as an optimal thickness (0,76 mm), means that the cards can be used worldwide (ISO, 1998).

The manufacturers interviewed in this study put all the information into a technical file and keep it for reference. If there was an incident with a piece of equipment, for example, the manufacturer would have to produce the technical file to a notified body immediately, and the notified body would look at it and assess whether they thought the manufacturer had done reasonable tests. If the manufacturer had done no tests for example, then there would be a problem. The maximum penalty of the Medical Devices Directive in the UK is £5,000 or 3 months in jail per offence (Bentley, 1998).

Many organisations have been pressurised into achieving certification to the standard. According to Somerton (1996)

We have design procedures laid down by ISO 9000 procedures which we follow. They are very broad outlines only. Each project is different and treated differently. Their whole test features that we have to comply with laid down, what is which we do. We just use ISO 9000 as a very broad outline guidance document.

Henderson (1997) also claimed that

for medical devices directive use, our quality system must be brought up to the standard ISO 9000. This is the main target to issue aim for.

Daughtery (1997) said,

At the moment we are looking again for ISO 9001 accreditation because that goes into the new design development area. ISO 9001 is very much formalized. Regulatory requirements are obviously very important for us - we have to conform to the medical device directive, whatever.

Henderson (1997) claimed

the business has, because it's legal requirement, a GMP approval, which is similar to ISO9002 which covers manufacturing. But, within new legislation if you start to produce equipment that has a therapeutic application rather than just a preventative nature, you have to have a control design process otherwise you have to be audited by a third party'.

The ISO maintains close working relations with regional groups of standards bodies. In practice, the members of such regional groups are also members of the ISO and the principle

is generally accepted that ISO standards are taken as the basis for whatever standards are required to meet the particular needs of a given geographical region (ISO, 1998).

7.4.2 USA, FDA (Food and Drug Administration) Approval

FDA approval is a medical device regulation in the USA. The FDA contains, 510(k) license approvals and GMP (Good Manufacturing Practice) approval.

7.4.2.1 Premarket Notifications -510(k)

Medical devices fall into 3 groups which are brand new devices, 'me too's' and common devices. The second group, devices which while not revolutionary still have a degree of complexity and risk associated with them, are required to be notified to the FDA prior to being marketed within the USA under section 510(k) of the Food, Drug and Cosmetic Act (Armstrong, 1998).

7.4.2.2 Good Manufacturing Practice programs

The GMP (Good Manufacturing Practice) requirements have been with medical device manufacturers for a number of years as a legal requirement. However, the QSR (Quality System Regulations) have considerably changed the playing field. The QSR's resulted from a desire to bring GMP more into line with ISO 9001. However there are large conceptual differences between a regulation backed by the force of law and punitive action, and an essentially voluntary International Standard (Armstrong, 1998).

Many device manufacturers have recently considerably notified their existing systems to meet ISO 9001/ EN 46001/CE Marking requirements, etc.

As discussed above, most manufacturers need to satisfy all product requirements which refer to safety, etc. but not to usability or users' opinions for use of products. Therefore, the next section discusses how manufacturers do take users' opinions into the design specification.

7.5 How manufacturers convert users' opinions into the design specification

All of the companies interviewed emphasised that they were very much concerned about customers and that users' opinions are fitted into the new product development process throughout a number of stages.

Before starting to discuss manufacturers’ actives for gathering users’ opinions, it is important to discuss the meaning of user groups. During the interviews the author found that the meaning of ‘user group’ varied. Users were not necessarily the real users. According to Anderson (1997), ethically and commercially, sales people can not directly talk to patients, therefore they normally approach technicians and nurses. Felding (1997) claimed that

The doctor is one customer, he is the one who prescribes treatment. The nurse is another customer, she is the one who learns from manufacturers and teaches the patients how to run the machine. She would say ‘I do not like this’. The technician is one customer, he is the one who is supposed to repair the machine. The administrator (purchasing officer) is one customer, she is the one who buys the machine on behalf of the organisation where it is used.

For the purposes of this research, the design process has been divided into four stages, which are early idea gathering stage, development stage, pre-production stage and product launch (see Table 7-4).

Manufacturers		Stage I	Stage II	Stage III	Stage IV
A & M Hearing Ltd.		○			○
Arjo Ltd.		○	○	○	○
Baxter Healthcare Ltd.		○	○		○
Clement Clarke International Ltd.		○			○
Drager Ltd.		○			○
Edale instruments		○			○
EMS Ltd.		○		○	○
Gambro		○			○
Gimson Stairlifts Ltd.		○		○	○
HNE Technology plc Group	Huntleigh Healthcare	○			○
	Huntleigh Kinetics	○	○	○	○
	Huntleigh Diagnostic	○			○
Medex Medical Ltd.		○			○
Medic-Aid Ltd.		○			○
Novamedix Ltd.		○			○
Oxford Instruments Ltd.		○			○

Table 7-4. Stages of obtaining customer opinions

Stage I. Early idea gathering stage

Most of the customers’ opinions are obtained by the sales and marketing department. Then the marketing department produces a marketing specification which they believe describes customers’ wants.

Somerton (1997) and Daughtery (1997) claim that for new product development, each company feeds from customers’ opinions and evaluate those opinions and if the new idea or suggestion is valid, that might be developed further into the specification.

According to Guy (1997) of Clement Clarke International Ltd., customer opinions are valuable. Although some of these opinions are impossible to implement, once they obtain users' opinions the manufacturers consider them when developing a new product. But after that, the users are not approached again nor asked their opinions because the market is quite sensitive and ideas are copied very quickly. Hobday (1997) of Oxford Instruments Ltd., further pointed out that a lot of customers are very good at seeing their present day requirements, but they are not very good at guessing what their requirements will be two years away.

Guess what is going to be required by users? So you have to speculate on occasions and some times you get it right, sometimes you get it wrong.

Type II manufacturers such as Baxter Healthcare Ltd., Drager Medical Ltd. and Gambro, obtain customer opinions as feedback from marketing and sales departments and report to headquarters on a regular base. Stansfield (1997) of Baxter Healthcare Ltd., said they obtain customer opinion from focus groups which consist of patients, nurses and doctors, and try to get a concept of what kind of features they want, and what price they expect (Daughtery, 1997). Sometimes they use questionnaire surveys for opinions about their equipment (Stansfield, 1997; Dexter, 1997). Anderson (1997), of Gambro, London, claims that they have close contact with a number of patient associations and their opinions are reported back to headquarters in Sweden.

Some manufacturers found that it is difficult to satisfy all the customers. Felding (1997) said,

If I speak to only one customer it might be a good idea for him but it will not be suitable for another person. That is sometimes treated as a problem, in that we need to make something that is both very universal and flexible. That is the challenge.

Daughtery (1997) claims that people in the health-care industry are actually saying what they want and what they do not like, but the company finds it very difficult to come up with a concept of what they would ideally like.

Stage II. Development stage

Some manufacturers such as Arjo Ltd., Baxter Healthcare Ltd. and Huntleigh Healthcare, organise focus groups during the development stage, to show customers what they are doing and ask them what they think.

Huntleigh Healthcare tends to organise a focus group to get a concept of basic marketing facts such as what kind of features people want in a product, what price they would expect to pay, what patients they would expect to treat on particular kinds of mattresses, how many patients they would want to use on them, etc. The focus groups are made up of a small group of community nurses, tissue viability nurses, ward sisters in generic places, etc.

In Arjo, the project team sets up a user group and this user group will normally consist of 4 or 5 people who are considered to be experts in their field. This would involve occupational therapists, ergonomists, physiotherapists etc. In fact, the user group or focus group is an ideal concept that Arjo would like to follow.

But although manufacturers claim to listen to customers, in reality, they may pay less attention. Forming user or focus groups is very time consuming, and often people do not want to take the time out to be involved. Therefore, once the manufactures have some initial feedback and they have done a design specification they tend to try to stick with that design specification and they would push that down to almost a finished product, because they believe they know what the market needs are (Daughtery, 1997).

Stage III. Pre-production stage

Blackburn (1997) of Gimson Stairlifts Ltd., claimed that once a prototype is developed they have two or three trials with local authorities. Wilton (1997) of EMS Ltd., said they also have trials for 1-2 or 3-4 units in the community to examine ease of use and effectiveness. Daughtery (1997) of Huntleigh Healthcare, claims that,

We actually do user preference trials where these products will be good enough for people to use as intended. We would get a selection of users, using selected hospitals, and people we know to give reliable feedback. Within that feedback we are able to check products we design and make them more suitable for the market we are aiming at.

Somerton (1997) claims that when the pre-production units have been built, they are used for field evaluation. Those 50 units typically will be sent to a number of different countries and will be used by patients, handlers or nurses, for something like 2 months. If there are any changes that are needed in design then obviously they have to go back through the loop again. If not, then it can be launched by the sister companies.

Huntleigh Healthcare does user studies or comfort trials of its products. The evaluation team covers up various Huntleigh Healthcare products and other companies' products with sheets. The testers move down three or four beds and rate the beds from the most comfortable to the most uncomfortable, etc. Generally 50% vote Huntleigh Healthcare's product as the most comfortable and 50% will say it is the most uncomfortable. So this proves that the perception of comfort is extremely subjective (Daughtery, 1997).

Stage IV. Product launch

All manufacturers claim to listen to customers' opinions about further product improvements. Brooks (1997) of Huntleigh Kinetics, claims that after launch their marketing and sales people demonstrate to the customer and receive feedback. Several manufacturers such as Gimson Stairlifts Ltd., Arjo Ltd., EMS Ltd. and Huntleigh Healthcare, have customer feedback through exhibitions, conferences and social services.

According to Somerton (1997) of Arjo Ltd., the company has good relations with its customers around the world and it continually receives feedback from customers and that is one reason for the success of its business.

There are a number of ways to convert customers' opinions into the design specification. Somerton (1997) of Arjo Ltd. claims that 'the marketing team will produce a specification which incorporates the features that the customers require. I will then take the marketing recommended specification and review it from a technical point of view, and produce a practical specification which is generally a compromise between the technical constraints and marketing wishes... the specification that we will use for the product design'. Wilton (1997) and Brooks (1997) claim that marketing or sales people produce proposals which contain customer opinion. They evaluate whether it is feasible or not and after that they produce primary specifications with detailed sketches, and then have comments from marketing, sales, production, and the quality control department. After that confirmation the project will be started.

Felding (1997) of Gambro said,

I write a lot of design specifications, but I am always discussing with my advisory board to make sure that it will be suitable for all applications. Otherwise, if I speak to one customer, the result might be a good idea for him, but it may not be so suitable for another person. That is sometime treated as a problem. We should

make something that is very universal and flexible... It is important to listen because there are different ideas.

Hobday (1997) of Oxford Instruments Ltd., claimed that the specification from marketing or product management will be what features it should have and its usability. It will not specify what it looks like or what is inside for the design. The design consultants will come back after they have seen the specification with proposals for the actual design, layout and architecture of the product.

We are specifying usability and features we want on it, so once that's gone then the design brief will come back from design engineers. We will look at that together to decide whether we progress from designing it to making a prototype.

As discussed in this section, customers' opinions are obtained at a number of stages and converted in a number of ways. It was also found that manufacturers have difficulties in converting feedback to the real product development.

7.6 Design procedures in new product development

This section discusses the design procedures in new product development. Only one manufacturer provided their product design procedure chart by mail and the majority of them did not provide them. Therefore, the design procedure charts produced in this section were obtained from interviewing manufacturers.

One reason why manufacturers do not provide or make public this actual design procedure, is that 'time to market' is a very important point. Therefore, manufacturers do not want other people to know about their own design process and their activity. New product development procedures involve many activities. The following sections, therefore, identify design procedures which would give actual activities for their new product development. To identify the design procedures of manufacturers is a way of trying to understand when users' opinions are obtained and how they are converted to the actual design development. When legislation procedures take place and how manufactures fit these into the design is all part of this plan. The design procedures very much depend on each project and their requirements, and this section gives general procedures.

7.6.1 Arjo Ltd.

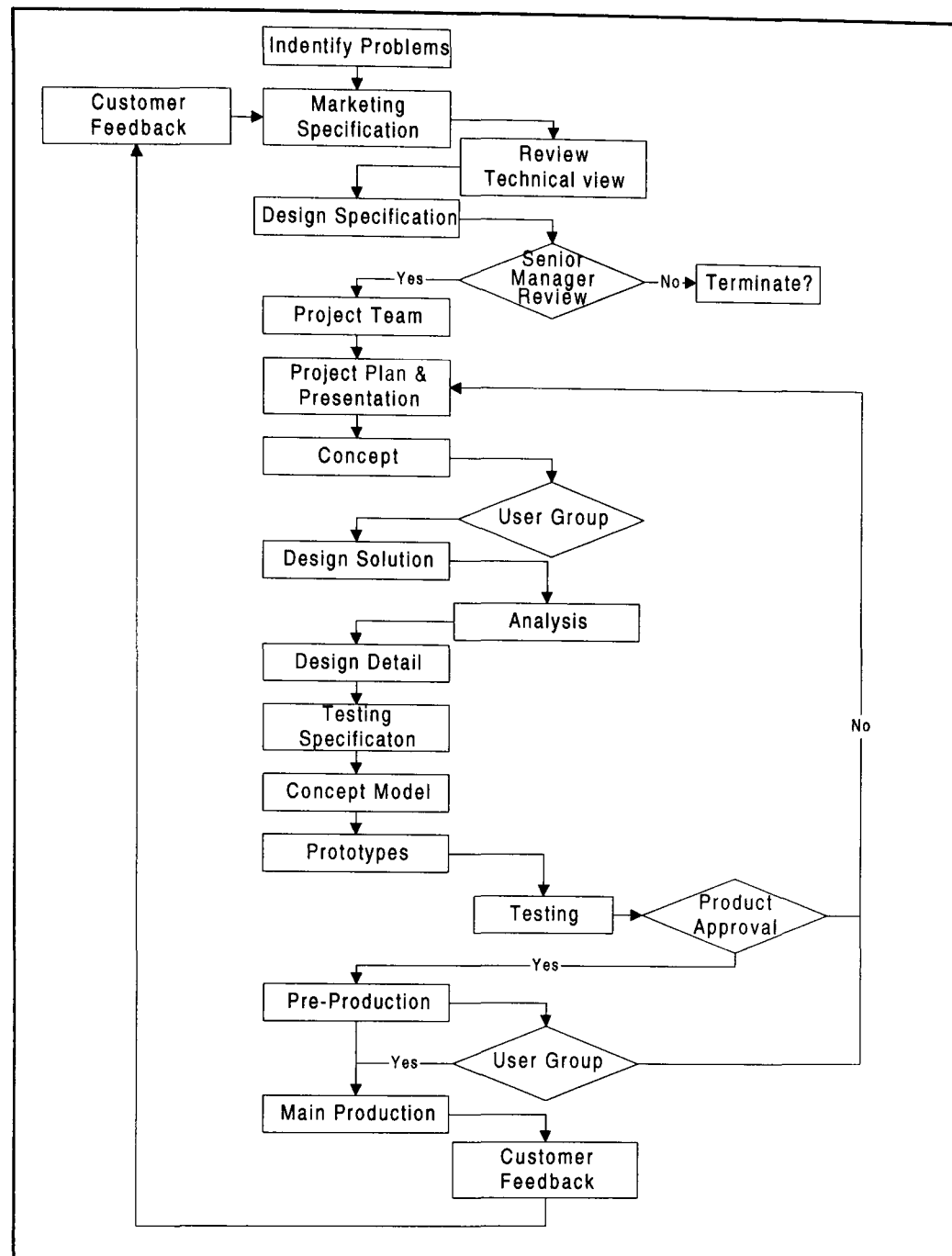


Figure 7-1. Design procedure - design process at Arjo Ltd.

(Constructed by S.Y. Lee-Interview at Arjo Ltd. with Mr. Somerton)

According to Somerton (1997), at Arjo Ltd., the project officially starts after a project plan and presentation from the project team. Design & development depends on how innovative the product has to be; either; looking at the development from an existing product or starting to think about new concepts and ideas. Regulatory approval work starts after they have design solutions and will be finished at product approval stage. Customer feedback is gained from the very beginning as well as after market launch, but Arjo Ltd. also sets up user groups for design solutions evaluation after the pre-production stage. The detail of the design procedures is discussed in Chapter 9, Arjo Ltd. case study.

7.6.2 Clement Clarke International Ltd.

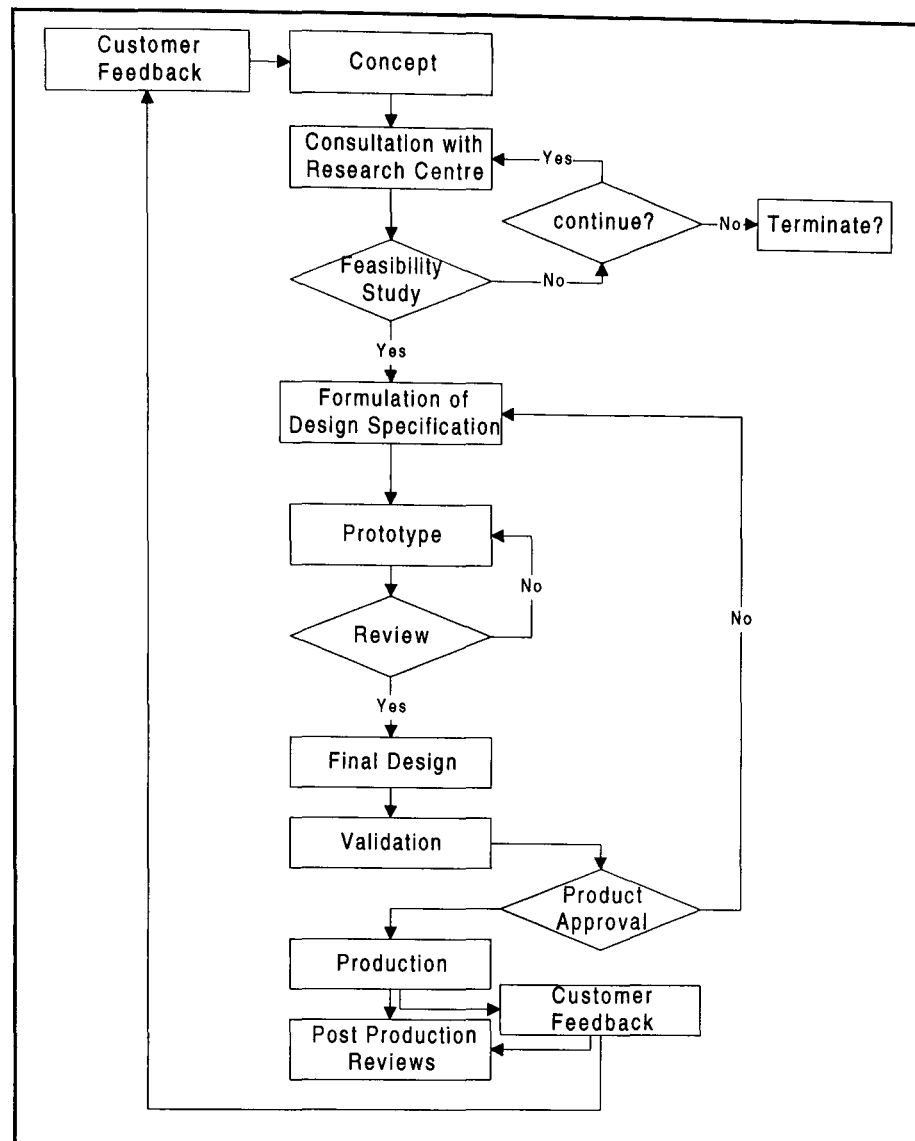


Figure 7-2. Design procedure - design process at Clement Clarke International Ltd.

(Constructed by S.Y. Lee-Interview at Clement Clarke International Ltd. with Mr. Guy)

According to Guy (1997), Clement Clarke International Ltd. normally develop a new product once a year, and other products will be produced by developing existing designs. Product design procedure there follows strictly standing instructions for ISO 9000 quality control.

Design specification is formulated through a feasibility study. The engineering design department is in charge of design and development and the formulation of the design specification stage. The design engineer starts detailing the design job and starts to look at regulatory approval work. Actual design & development work will be finished after the preliminary design stage. Then they will validate their designing work and they will proceed to the final product approval. Customer feedback take places at the very beginning of the process and after the pre-production stage.

7.6.3 EMS (Electro Medical Supplies) Ltd.

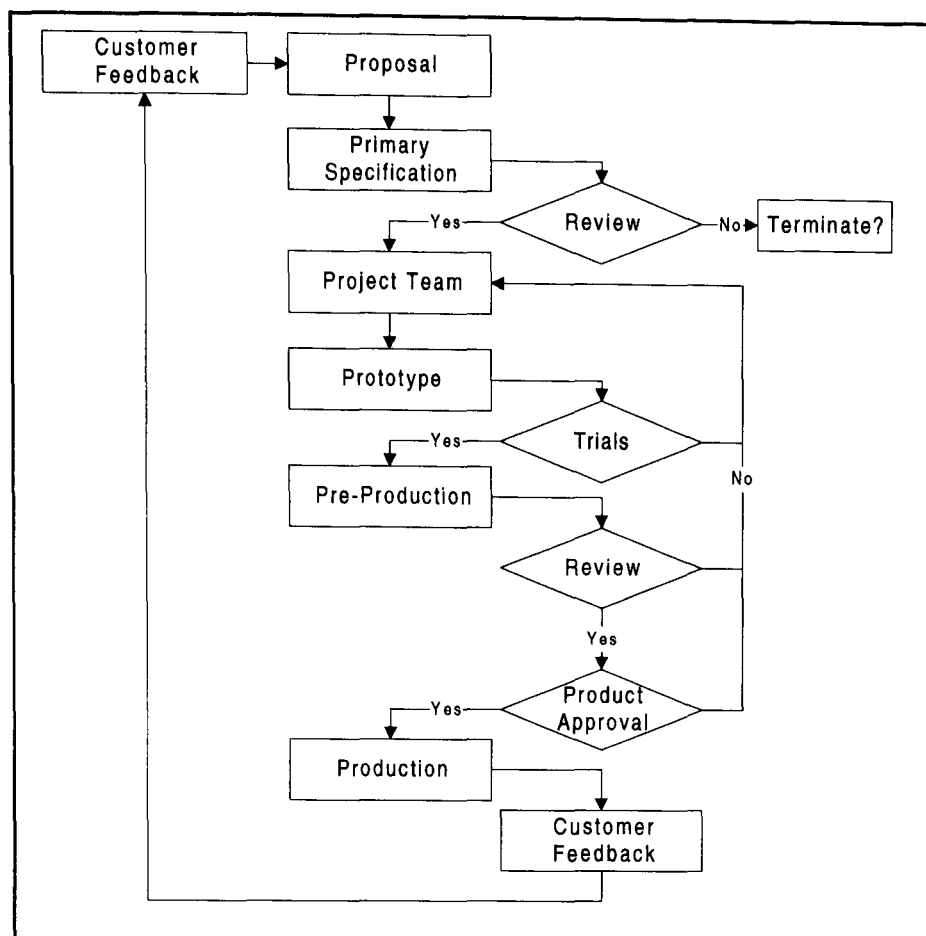


Figure 7-3. Design procedure - design process at EMS Ltd.

(Constructed by S.Y. Lee-Interview at EMS Ltd. with Mr. Wilton)

According to Wilton (1997) of EMS Ltd., the whole product development procedure take 12 to 18 months. The design & development stage starts after a project team is formed and during this stage they have progress meetings every week and product review meetings once a month.

The design department consists of six people who are design engineers and electricians and they also try to solve regulatory work and product approval. At this stage most of their work will be finished. In the designing of physiotherapy equipment, a general problem is generating energy. In the case of short wave therapy equipment, 300 - 400 watt short wave radiation is required; therefore the risk to patients and safety analysis of patient use are very important in the process of the design work.

Customer feedback is gained from the very beginning of the process and after a launch to market with a sales department demonstration, but also they have customer trials to find out if that equipment is easy to use and effective.

7.6.4 Huntleigh Healthcare

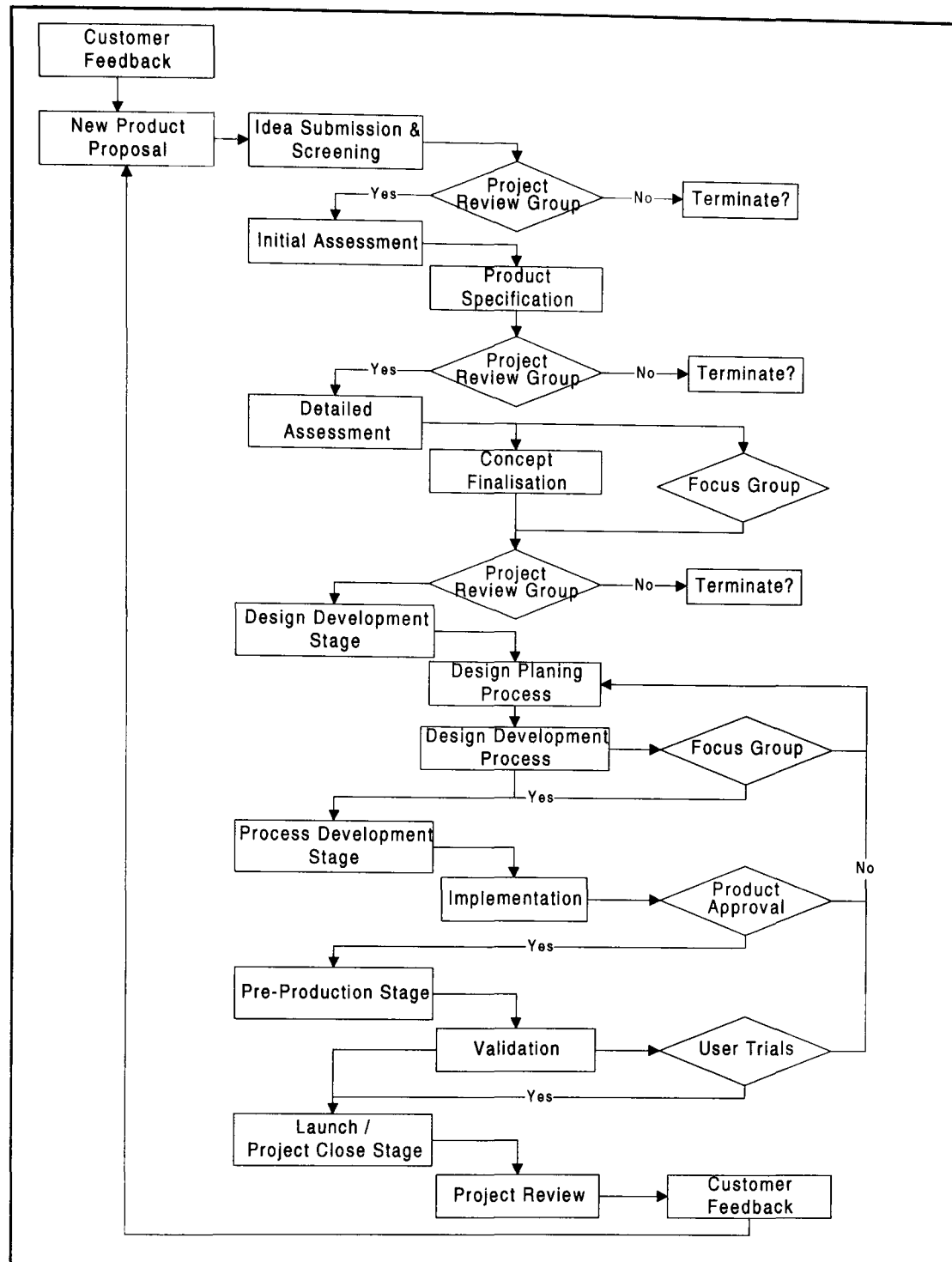


Figure 7-4. Design procedure - design process at Huntleigh Healthcare

(Constructed by S.Y. Lee-Interview at Huntleigh Healthcare with Mr. Henderson)

According to Henderson (1997) Huntleigh Healthcare, at the product specification stage start to consider regulatory approval work and this will be finished during the product approval stage. At the design development stage they work for detailing the design of the job and this will be completed with implementation. Customer feedback is gained from the very beginning of the stage and after launch to market but they also set up focus groups for the detailed assessment stage and the design development stage. The detail of the design procedures will be discussed in Chapter 8, HNE Technology plc Group case study.

7.6.5 Medic-Aid Ltd.

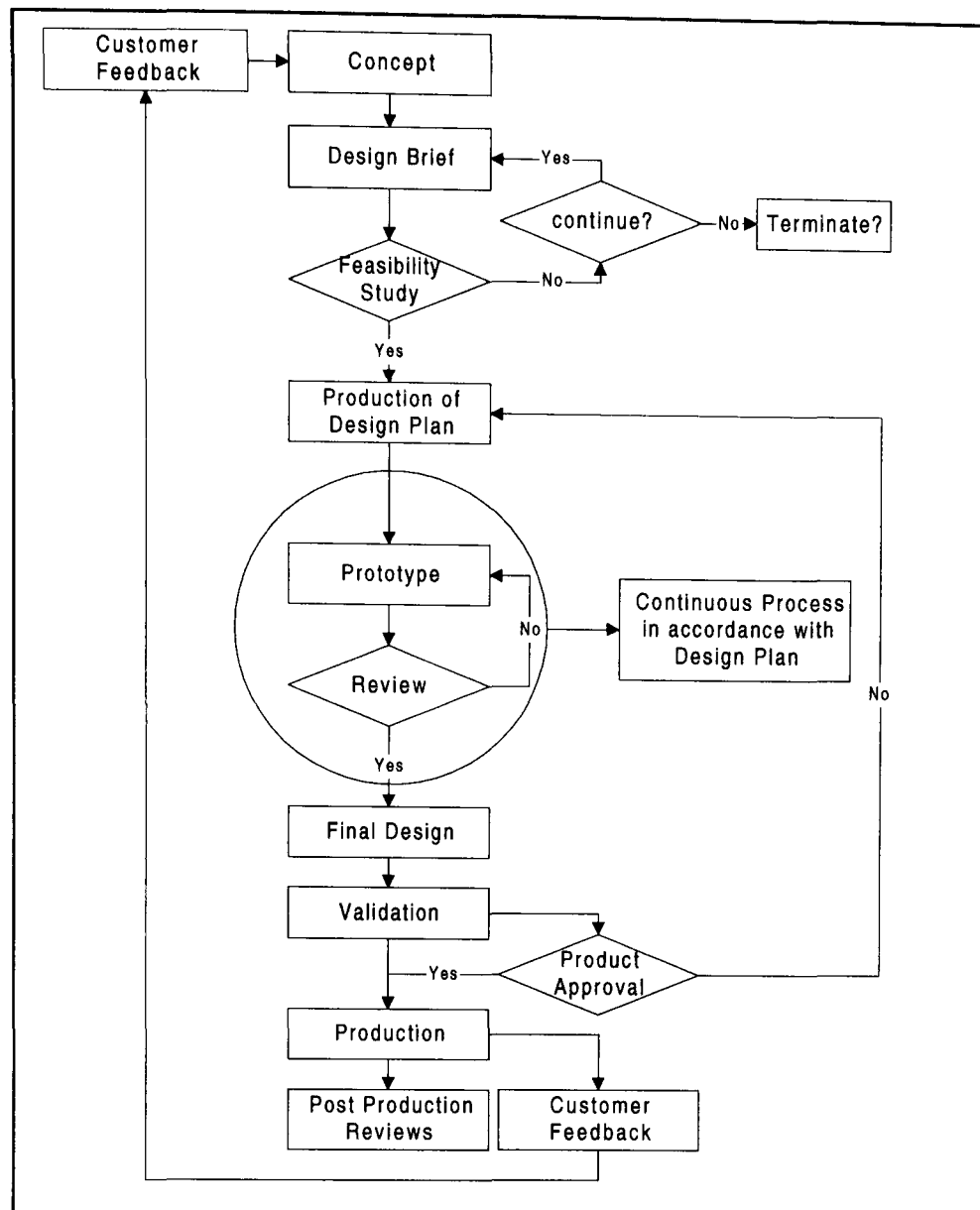


Figure 7-5. Design procedure - design process at Medic-Aid Ltd.

(Provided by Ms. Dexter at Medic-Aid Ltd., by postal questionnaires)

According to Dexter (1997) Medic-Aid Ltd.'s, R&D department consists of 4 design engineers, 2 laboratory assistants and 2 others. Design and development work starts the production of the design plan stage and they also harmonize standards with regulatory requirements and safety requirements. The work is completed at the product approval stage.

At the review stage clinical trials and risk analysis checks are carried out. At the validation stage safety, reliability and performance are also considered.

Customer opinions are gained from patient panels, health professional panels and ongoing research.

7.6.6 Gambro

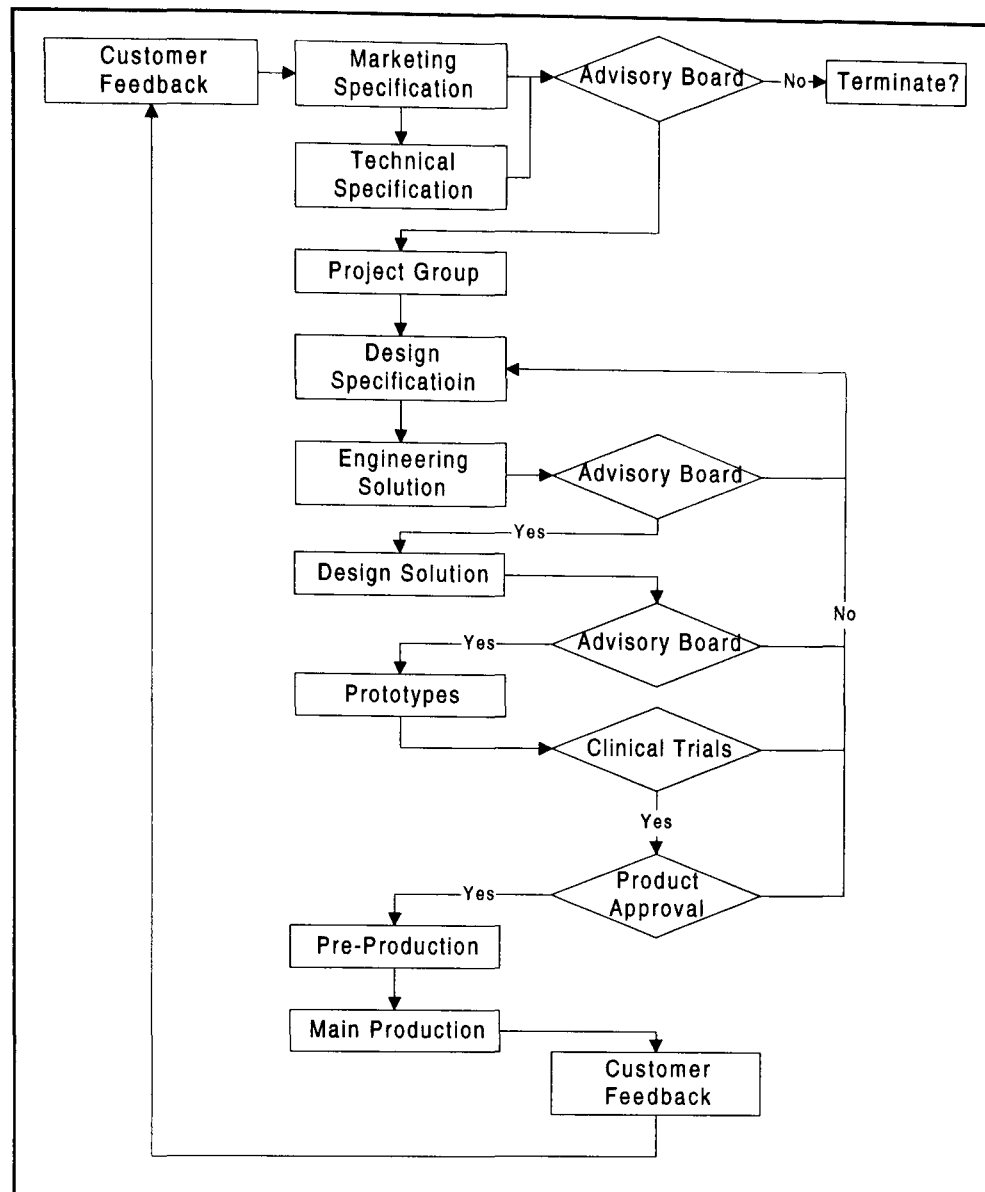


Figure 7-6. Design procedure - design process at Gambro
(Constructed by S.Y. Lee-Interview at Gambro with Mr. Felding)

According to Felding (1997), the design engineering department of Gambro in Sweden consists of hardware and software engineers who develop new products and new software. The design specification stage follows by after the project group has been formed. Engineering design & development starts and regulatory approval work starts at this stage and both end at the product approval stage. At the design solution stage they involve industrial designers from outside the company and give casing design.

Customer feedback is gained from the very beginning of the process and after launch to market but also they have clinical trials after the prototype development stage. The detail of the design procedures will be discussed in Chapter 10, Gambro case study.

7.6.7 Oxford Instruments Ltd.

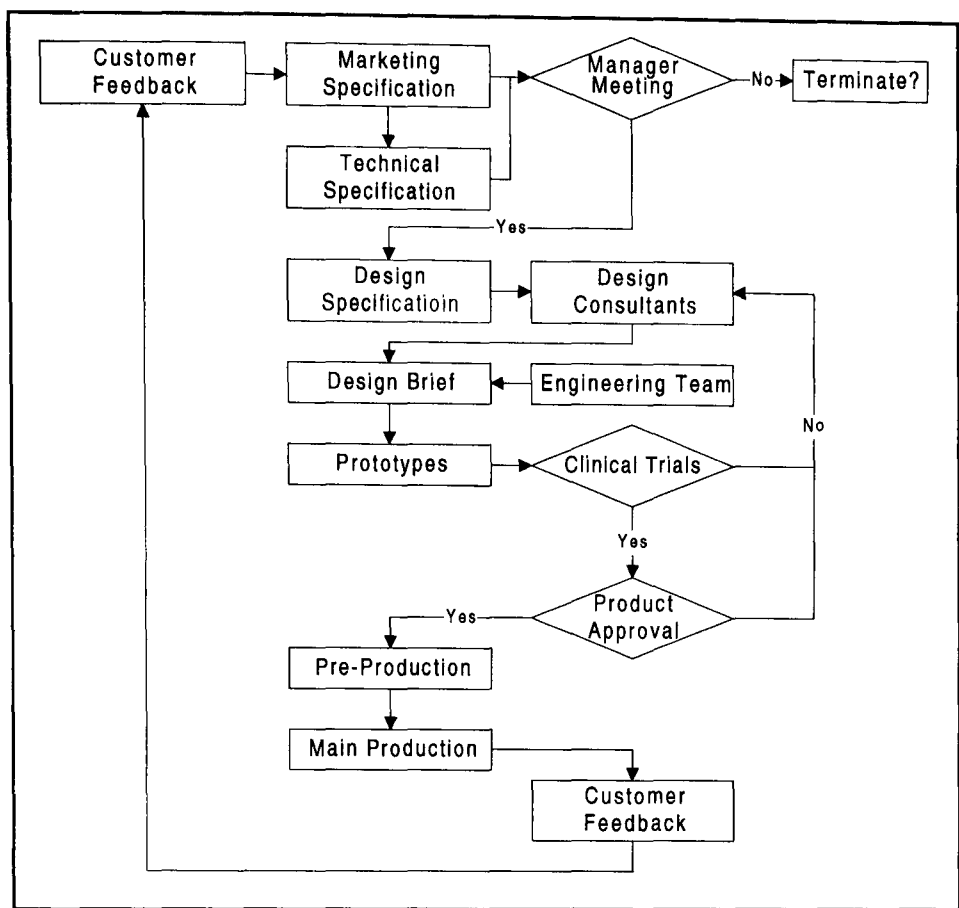


Figure 7-7. Design procedure - design process at Oxford Instruments Ltd.

(Constructed by S.Y. Lee-Interview at Oxford Instrument Ltd. with Ms. Hobday)

According to Hobday (1997), at Oxford Instrument Ltd. the R&D department has 30 design engineers who develop hardware, software and firmware, and work very closely with design consultants. The design consultants propose their designing work for Oxford Instruments Ltd. Normally, they specify usability and features which Oxford Instruments Ltd. wanted and this relationship goes until the prototypes stage. Product modification work happens often and it takes 6 months to 1 year and they would add some other features to compete.

The regulatory approval work has a great impact and in order to meet the latest approval the company has sometimes had to redesign products.

Customer feedback takes place at the very beginning of the process and after launch to market; but customers are usually less involved with input for new product developments.

7.6.8 Novamedix Ltd.

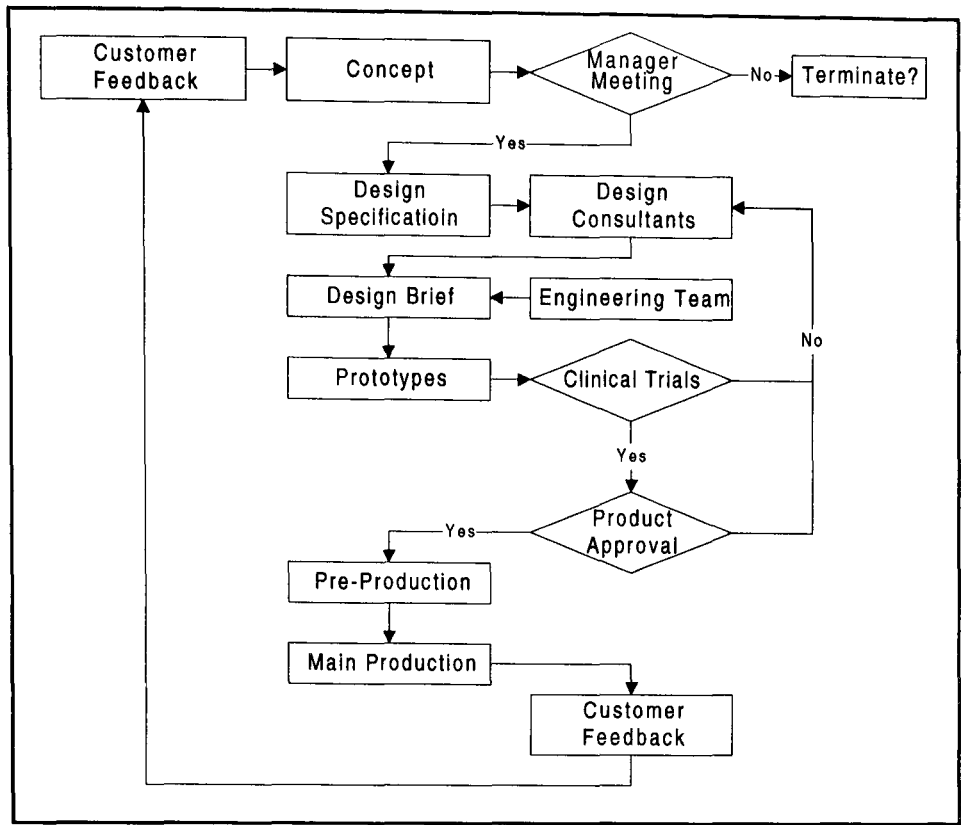


Figure 7-8. Design procedure - design process at Novamedix Ltd.

(Constructed by S.Y. Lee-Interview at Novamedix Ltd. with Mr. Brown)

According to Brown (1997), Novamedix Ltd.’s design engineering department has 4 design engineers and when they have new product development they ask design consultants to present their design works.

The design process is constantly up dated by regulatory approval work and the design specification stage sets clear strategic systems for ISO 9000 processes and these will be completed by product approval stage.

Customer feedback is gained from the very beginning of the process and after launch to market but also they have clinical trials after the prototype development stage.

7.7 Manufacturers' understanding of design

Wilton (1997) of EMS Ltd., claims that initial impression is important, therefore, a design must give good visual impact and design should consider ergonomics. Designing a control panel involves user interface for electronic equipment and also needs to indicate any safety instructions.

Brooks (1997) of Huntleigh Kinetics, claims that the role of design for product development very much involves ideas, the original concept for the product requirement, sketch and implication.

Baily (1997) of Huntleigh Diagnostic, claims design means that;

to develop innovative new ideas and new applications, to work in conjunction with all the other departments, in formulating them, turn those ideas to physical reality with constraints of product cost, development time frames, development costs and then to put that into production. Within our role, we also support production and on going activities particularly changing supplier. So, we also do on going manufacturing support. That is the role of our Engineering section. Product design is one of their responsibilities. Design is one small part of that.

Brown (1997) claims that design is 'why and where it's been used' and 'trying to understand a product'.

According to the interviewees, the real understanding of design is very much to do with visual work and very much seen as a small part of the overall production of a piece of equipment.

7.8 Current market trends and future expectation

The home health-care market is expanding rapidly. Many manufacturers agreed that the future for the home health-care market is bright.

Blackburn (1997) of Gimson Stairlifts Ltd., claimed that their stairlift market is expanding; last year 23,000 stairlifts were sold within the UK. Anderson (1997) of Gambro in London, claims that the UK home dialysis market is preeminent, and their sales in Germany and Holland are very strong for home dialysis. According to Brown (1997) of Novamedix Ltd., their business is growing very rapidly; they sold \$10 million

last year and the potential for this market is perhaps more than \$100 million. He further said, 'We are very successful in the USA and distributors who sell to the home care market keep on telling us that this is the future. The home care market is at least twice the size of the hospital market'.

Daughtery (1997) of Huntleigh Healthcare claimed that,

We are seeing a big rise in the number of people treated in the home with care in the community and specialist nursing homes, so we are beginning to catch that market a little bit more.

Somerton (1997) of Arjo Ltd., also claims that in their market especially nursing home area, residential home areas are rising.

Morrissey (1997) of Applied Medical Technology Ltd., claimed that their sales in the UK are not good because when customers buy certain products, funding does not come from the health authority. Outside the UK, for example in the USA, Germany, France, etc., there is quite a strong use of insulin, because those countries have funded insurance or health authorities. Pattinson (1997) Drager Medical Ltd., agreed that the home market is growing in the USA and Europe but especially in UK financial pressure is coming on to hospitals and that is one reason the UK market is growing less than others.

Hobday (1997) of Oxford Instruments Ltd., claimed that

The home health-care market is obviously expanding, but it is very much depends what market you are selling into, somewhere like Germany or USA, it doesn't matter how good your product is. If you can not get the insurance company to pay for using it, you will not sell it. So you have to get the insurance company to say 'Yes, we will pay reimbursement for that procedure to be done at home'.

Brown (1997) of Novamedix Ltd., claimed that insurance reimbursement is very widely practiced in the USA. The private health-care system and health insurance will pay for this treatment at home. If somebody who wants to take a machine home with them to continue their therapy at home, they have to have reimbursement first.

According to Wilton (1997) of EMS Ltd., the home health-care market is not expanding in the electrotherapy equipment industry. Two of their competitors had disappeared in the last 18 months and the last 2-3 years had seen much the same level. The customers they are selling to are different nowadays. Whereas many years ago the NHS was their

main customer, today it is the GP.

Daughtery (1997) of Huntleigh Healthcare claims that in a hospital environment, a nurse or care comes regularly to check the patient, but in the home environment a non-technical person may be left alone. This gives a reason for developing a simple and safe product for the home.

Brown (1997) of Novamedix Ltd., said hospitals are trying to discharge patients as soon as possible to get patients home because it costs less for the hospital.

Daughtery (1997) of Huntleigh Healthcare, claims that

In Britain there is not that much differentiation between the hospital market and home care market in our business area. We tend to design our products more based towards the hospital market and they are naturally going to the home care market.

A number of manufacturers including Daughtery (1997) of Huntleigh Healthcare, Anderson (1997) of Gambro in London, Felding (1997) of Gambro in Sweden pointed out that to make things simpler and easier, not more complex, is the key drive for the home care market.

Brown (1997) of Novamedix Ltd., believed

In my opinion, the UK follows USA trends, sometimes 10years afterwards, but when I visit the USA, for example, pharmacist and chemist drug stores are full of treatment and equipment that you wouldn't find in the UK easily; only in London but not in the provinces. Let's say blood pressure, 5 years ago you couldn't. Now you can, from Boots, wherever. The trend is that, for example, my mother has high blood pressure and GP said she must have a blood pressure monitor so I bought one for her. But, 5 years ago the GP would say you need to come regularly to the clinic and you need to be monitored. Now you can do this at home. We recognised that patients have money for health-care.

Baily (1997) of Huntleigh Diagnostic, claimed that

I think there will be more useful equipment in the home, but not necessarily looked after by patients, but by a clinician who will be devolved away from hospitals. If you put in diagnostic equipment you need to be trained in order to interpret it.

Hobday (1997) of Oxford Instruments Ltd., claims that

In America, which is a very large country, there have been trends recently for monitoring elderly people at home by putting video cameras and you then have a station with a nurse who will go around over the telephone or video line to look at these elderly people so geographically covering a big area. If someone burns

his/her hand today they hold up their hand on camera by looking at the burn.... definitely trends towards doing more at home.... it's cheaper'.

Stansfield (1997) of Baxter Healthcare Ltd., claims that the next generation of equipment would be smaller and easier to use, because there are more older people and they are the non computerised generation. Currently Baxter Healthcare Ltd. is developing equipment that is easy to program. For example, if somebody needed to change a program they would simply phone up through the modem, and swap the equipment using a smart card. The equipment would then automatically detect the specific patient and give a correct programming for him/her.

7.9 Overall findings of the manufacturer interviews

Legal requirements for the European Union and the United States cause tremendous impact on design procedures for the manufacturers. Most of the interviewees recognised the growing importance of regulations and standards including ISO 9000, CE Mark, GMP, 510K, etc. The manufacturers need to satisfy all product requirements which focus on the safety aspects rather than user's point of view.

All of the companies emphasise that they are very much concerned about customers and users' opinions are fitted into the new product development process throughout a number of stages; for example, early idea gathering stage, development stage, pre-production stage and product launch. However, it was also found that manufacturers have difficulties in converting feedback to the real product development.

It seems that users opinions have a minimal place in the design process. Time to market and regulatory matters are more important, although all of the companies emphasised that they are very much concerned about customers' and users' opinions.

Manufacturers' understanding of industrial design is that it is visual work and very much a small part of 'real' design i.e. engineering design, although some manufacturers recognised the importance of design, in that design can make things simpler and easier, not more complex, which they stress is the key drive for the home care market.

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Chapter 8

HNE Healthcare plc Group

CHAPTER 8. *HNE TECHNOLOGY PLC GROUP*

8.1 *Introduction*

This case study provides examples of product development in an international firm. The Huntleigh Nesbit Evans (HNE) Technology plc (Public Limited Company) Group has 11 divisions within the UK. Among these, three divisions have been involved for this case study, viz., Huntleigh Healthcare, Huntleigh Diagnostics and Huntleigh Kinetics. Each division operates fairly autonomously. Three examples of product development involving these three divisions are described. Section 2 depicts HNE Technology plc Group and its products, and the relationship between the division and the parent headquarters.

Section 8.3 describes Huntleigh Healthcare in Luton, whose main interest is making advanced mattress systems. Section 8.4 discusses the design department within the organisational structure. Section 8.5 describes new product development. Section 8.6 discusses new product development processes. Section 8.7 describes how a chosen product, the Micro pump, was changed and developed.

Section 8 describes Huntleigh Diagnostics in Cardiff, whose main interest is making medical equipment for vascular and obstetric medicine. Section 9 discusses the design department within the organisation structure and their new product development. Section 10 describes how a chosen product, the BD4000, was changed and developed.

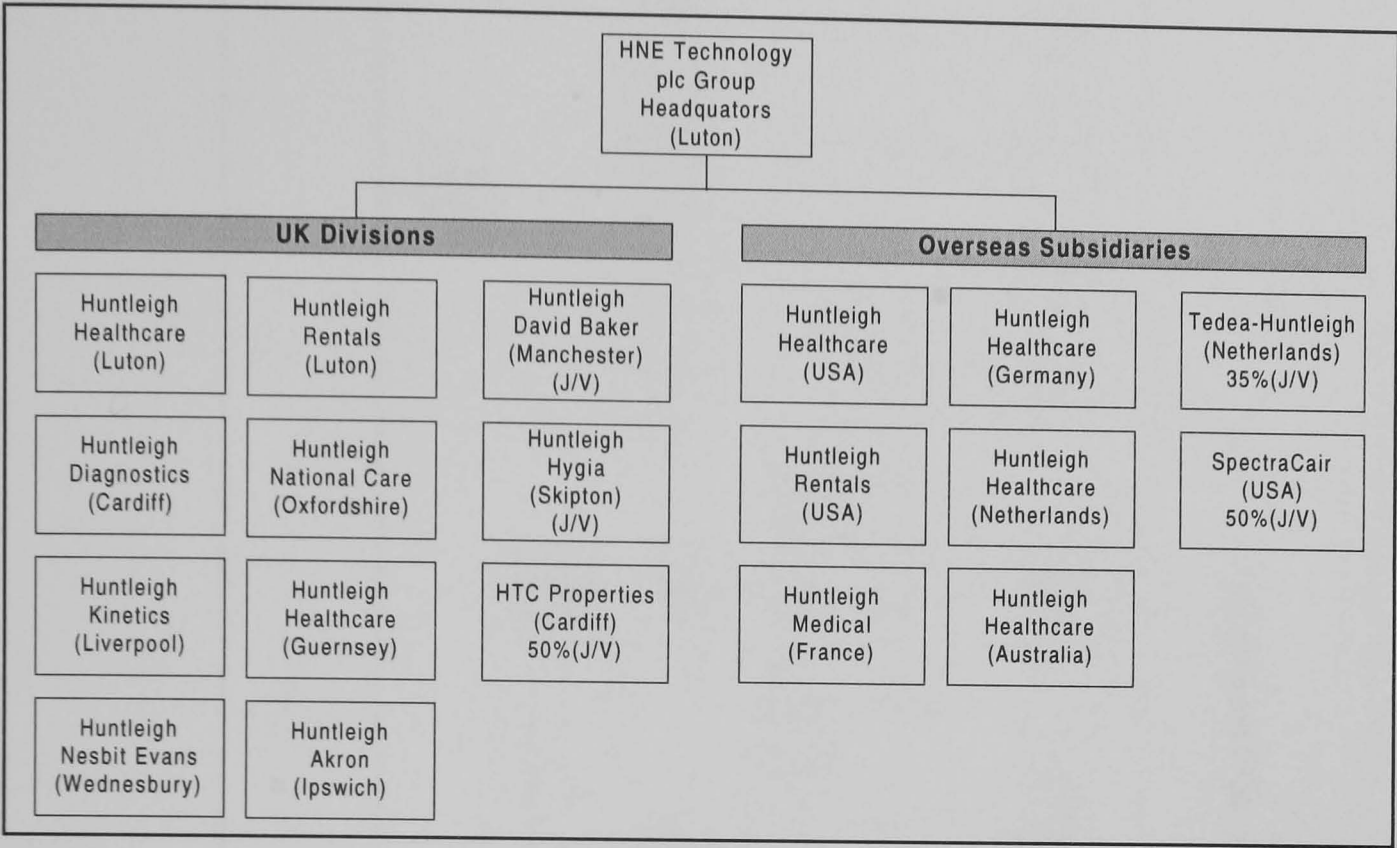
Section 11 describes Huntleigh Kinetics in Liverpool, whose main interest is making community care products. Section 12 discusses the design department within the organisational structure and their new product development. Section 13 describes how a chosen product, the Pisces, was changed and developed. Section 14 summarises the pattern as regards new product development by Huntleigh's design team.

8.2 *Huntleigh Nesbit Evans Technology plc Group.*

Huntleigh Nesbit Evans Technology plc Group is a British firm, which consists of 11 United Kingdom based divisions and 8 overseas subsidiaries and among these, 3 divisions are joint venture companies (see Figure. 8-1).

Figure 8-1. Operational structure (source: HNE Technology plc Group Annual Report, 1996)

J/V = Joint venture company



HNE Technology plc Group, the parent company of Huntleigh Healthcare, acquired the Nesbit Evans Group to form Huntleigh Nesbit Evans Technology plc Group in 1995.

The new HNE Technology plc Group provides a wide range of equipment for the medical and consumer industries. Product ranges include: medical beds, medical conveyers, hospital furniture, physiotherapy equipment, hospital trolleys and mobility aids, such as lifts and hoists. It also supplies diagnostic equipment and a full range of furnishing systems for hotels and student and nursing homes (see Figures 8-2 & 8-3).

In 1996, the UK companies within HNE Technology plc Group had a total of 1,279 employees. In 1996, the HNE Technology plc Group achieved an annual turnover of about £91m, of which about £40m was from Huntleigh Healthcare in the UK (see Table 8-1).

Table 8-1. Turnover (source: HNE Technology plc Group Annual Report, 1996)

Geographical Destination	Turnover(£'000)
United Kingdom	40,058
Europe	18,244
United States	25,482
Rest of the World	8,122
Total	91,906

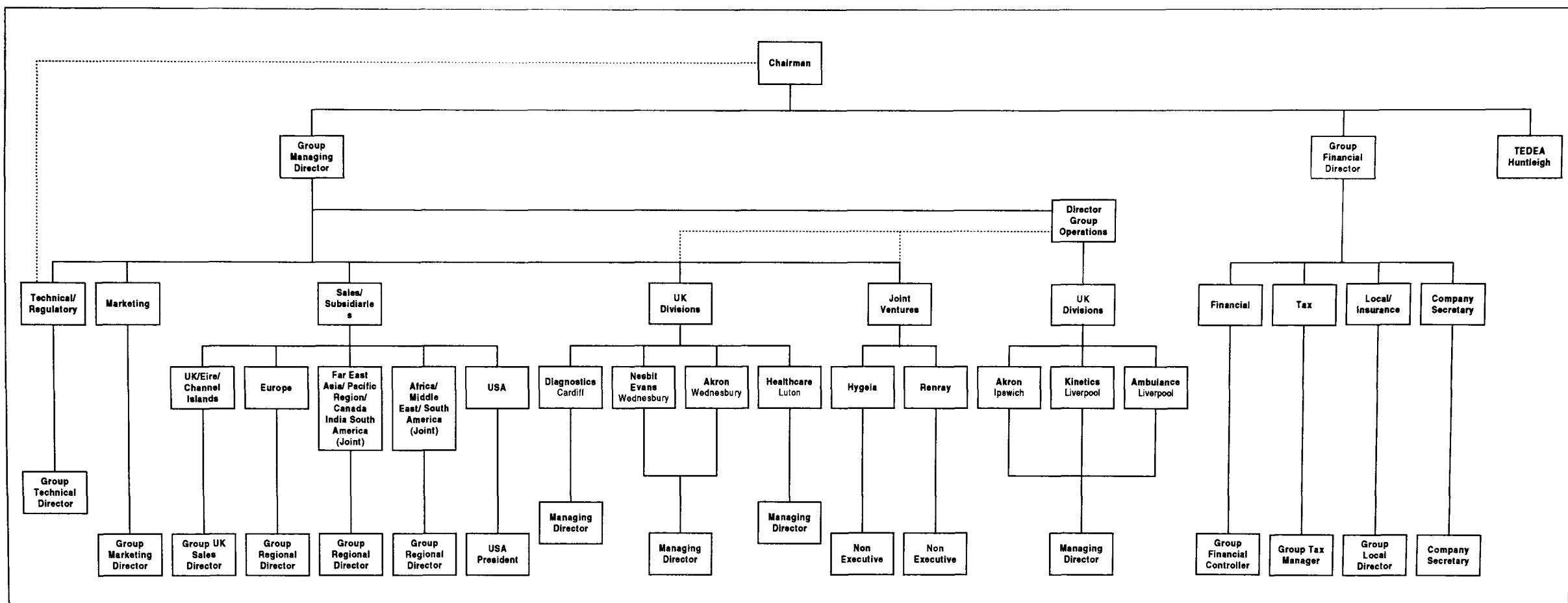
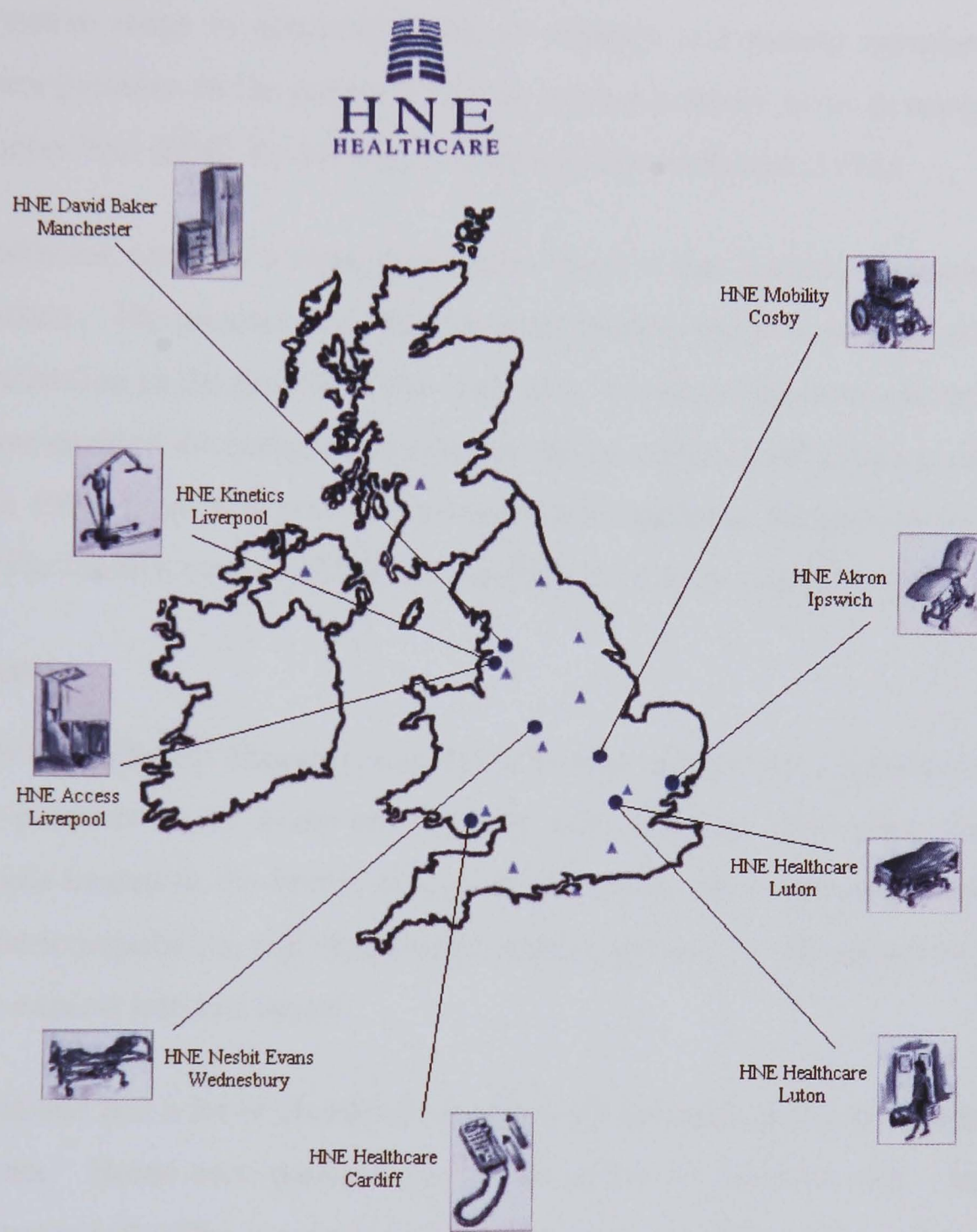


Figure 8-2. HNE Technology plc Group corporate structure (1997)



▲ UK Rental Service Centres

Figure 8-3. Huntleigh UK product manufacturing divisions

(Source: HNE Community Care, 1994)

8.3 *Huntleigh Healthcare (Luton)*

Huntleigh Healthcare is one of the world's leading manufacturers of advanced mattress systems for the care of patients assessed to be at risk of developing pressure sores. The division's extensive range of specially designed mattress and seating systems actively relieve or reduce pressure on the patient's skin to prevent pressure sores developing or to help existing sores heal (HNE Technology plc Group Annual Report, 1996).

Huntleigh Healthcare operates a large direct sales force in the hospital, community and home care markets. The pressure area management product range continues to make an important contribution to the growth of the company. Increased resources in the clinical department have enabled the company to enhance the educational and support activities it undertakes. In 1995, there was growth on export developments, particularly in the East European and Far Eastern markets (HNE Technology plc Group Annual Report, 1996).

8.3.1 *Home care*

Daughtery (1997), Technical Manager, stated that there is an increasing number of people who use their products in the home environment and there has been a big rise in the number of people treated in the home, as a result of care in the community policies, the rise of the geriatric population, and of specialist nursing homes. So Huntleigh Healthcare is beginning to expand into this sector.

He further explained that a lot of Huntleigh Healthcare's products move downward to the needs of patients. Home care patients tend to be a low to medium risk. However, sometimes a person will suffer a period of neglect at home possibly resulting from a wish to remain independent but being unable to cope. Such people tend to be geriatric or elderly grandmothers or grandfathers who are still living at home, who tend to spend more and more time in bed and, therefore, are at risk of developing sores. If they tend to get malnutrition, or diseases such as diabetes, or if such people put on a lot of weight and so cannot be moved at all and spend all day in bed then they move slowly up the risk scale. After a while, a point can be reached when those people might not be able to be nursed at home, to such an extent that nursing homes, geriatric care or hospitals would probably need to take over (Daughtery, 1997).

However, usage of home care equipment is increasing and many home care products are used by people with disabilities and this factor needs to be taken into account when designing a product for them.

8.3.2 Training

When products are put into the market, in the home care environment, the company trains their delivery drivers so that these drivers can teach users of the products how to operate the equipment correctly, what users need to look for, and how users need to operate it.

Daughtery stated that the delivery drivers have clinical training. They assess, for instance, whether the patients have been allocated the right type of equipment and install it correctly for them, and actually do some monitoring of what happens.

Daughtery claimed,

Here I think part of the strength of our business is that we do not really like to see ourselves as a product delivery firm, we consider ourselves a service delivering firm, of which the product is part of the service. So our drivers are well trained to be able to teach people how to use the equipment.

If the person who uses the product had difficulty in using the equipment, for instance, in turning pressure control knobs because of bad arthritis or disablement etc., the drivers would note that problem on returning and they would contact the local area manager of the company. They would then contact the social services or local hospital to explain that they felt that this product and this patient perhaps needed more care and, they would get the social services going on a more regular basis to deal with it (Daughtery, 1997).

However, the home care market tends to be extremely cost-based and this factor is borne in mind by Huntleigh Healthcare. This market usually needs extremely cheap or cost effective products and consequently, the amount of expertise which can be put in a product (e.g. the Micro pump) is limited. So Huntleigh Healthcare try to keep the product down to a simple system - perhaps a simple pressure control.

8.3.3 Customer opinion feedback

Daughtery stated that one reason why Huntleigh Healthcare is such a large company today is that in the past, the company went totally against market opinion. For example, when the company first examined the market many years ago the market did not really

want a product such as the Nimbus which is an advanced dynamic flotation system to prevent the development of pressure sores for patients at very high risk. There was no market need for it, because there was no similar product on the market, therefore demand was not really driven by the market. However, the chairman saw the potential in a new product and drove through a lot of the concepts himself, and the Nimbus product has since become a very successful product.

As the company continued to expand it tended to organise many more focus groups through the marketing department, basically on the work side so that now, user preference trials and focus groups are involved very early on in a project.

Daughtery explained,

We are trying to get out and discuss with the people - little groups of community nurses, tissue viability nurses, ward sisters in generic places, so we form them into little groups and we try to discuss what their needs are, their current usage of products, what they find good in the product, what they find bad in the product, what they would find to be their ideal product if they could have one.

8.3.4 Complaints system

Within the company there is a complaints system which is regularly reviewed, to try to see if there are any problems in the home and hospital care field. An example of how this system works can be seen with the Nimbus product which is in Huntleigh Healthcare's top range and quite a sophisticated product, substantially used for the hospital market.

However, it is also used in home care, and the company can end up with various problems in the home care market.

One lady rang the other day. She has a Nimbus set up at home, but she tends to spend a large amount of her time on her own. What happens in her area, they are doing some new building work so she tends to have power cuts. The workmen cut the cable down. Consequently, the pump stops working, the mattress deflates so if the pump stops the alarm goes. Her problem is the fact that she has no carer available for that period of time. She was on her own and she can't actually deal with that knob. She can't actually move to get to it (Daughtery, 1997).

At that point the company noted the telephone call and logged her complaint and comments into the complaints system. Daughtery claimed that the complaints system works by customer enquiries and is also used for further development of the product based on user comments.

8.3.5 Rental division

Huntleigh has a large rental division. Daughtery explained that when many hospitals get a new patient in, the company guarantee to have a mattress under them in 4 hours. They take old beds away, put a new one in and Huntleigh Healthcare has its own laundry system so the old beds go into the laundry and come back out into the rental fleet, ready for the next customer. So there are thousands of systems out on rental and at present the company is trying to tender for rental beds for a whole hospital or hospital group.

8.3.6 Evaluation department

Whenever any brand new products are launched by a competitor, the company take them in and evaluate them. With beds, for example, both weighted machines and humans are used to provide a weight test for performance assessment.

Huntleigh Healthcare does user studies or comfort trials of its products and, where possible, tries to do them 'blind'. This means that testers come to the Luton site and then the evaluation team cover up various Huntleigh Healthcare's products and other companies products with sheets. The testers move down three or four beds and rate the beds from the most comfortable to the most uncomfortable, etc. Generally 50% vote Huntleigh Healthcare's product as the most comfortable and 50% will say it is the most uncomfortable. So this proves that the perception of comfort is extremely subjective (Daughtery, 1997).

With a big mattress such as the Nimbus product, the cells move down quite a bit. People who are in a lot of pain or who are very light sleepers tend to see such a characteristic as very uncomfortable even though it is very good therapy for them. If the slightest movement causes them pain Huntleigh Healthcare have some systems that move very slowly.

This is extremely comfortable because of the slow movement but, at the same time, some people do not always like this alternative precisely because it moves too slowly'. That is where people will see major comfort or major pain issues subjectively and is very difficult to control because such issues are very individual to people's physiological aspects (Daughtery, 1997).

Huntleigh Healthcare finds that it can be very difficult to cater for the home care type market since perceptions of major comfort or major pain issues are so individual to a

person's physiological aspects. Such a difficulty is further compounded at an international level by factors beyond Huntleigh Healthcare's control, such as variations in clinical training from country to country or variable national price-led systems.

8.4 The design department within the organisation structure

There are five manufacturing divisions within the HNE Technology plc Group and each division operates fairly autonomously. The group technical director is working towards unifying the divisional research and development (R&D) operations bringing each R&D division up to the same level of effectiveness as that of the Luton site, which leads at present. Each division has a technical manager and they are in charge of product development. The R&D operations which are at a lower level in some divisions may only have amounted to cloning of existing market leaders. Sometimes they are a result of reactive rather than proactive development (Harding, 1998a).

Each division has an engineering department team, normally involved with design and development but in the past they also had an inter linked relationship with the Cardiff division design & development department in which they had an industrial designer.

The group technical director is involved with most projects, working with the group industrial designer as a team. As a team at group level, the group technical director and the group industrial designer role includes: implementing commercial objectives of group and risk management, and providing a support role for manufacturing and distribution divisions; also to enthuse, educate, help, motivate and investigate, with deference. There are no authorities directly linked with them. Their roles are in the areas of education, active watchdog and specialist contribution (Harding, 1998a).

As a group industrial designer, the role can be summarised on a macro and micro level. Macro roles are to contribute to the design process of new products across the group, to encourage a user-centred approach to design, to share knowledge of healthcare design within the group, and to compliment the role of the marketing department. Micro roles are to identify users, research their needs in target markets, and to prepare initial design criteria based on the research. As a design team member, it is also to ensure a product matches users' needs, and prepare 2D and 3D design concepts to agreed criteria, and to

provide on going consultancy throughout product development (Harding, 1998b).

The following examples describe how an industrial designer collaborates with research and development (R&D) in terms of design and development (Harding, 1998b).

Example 1

Front end research on moving and handling with hoists and slings was followed by action being taken by that division responsible for the hoist production to change the design and service provided in the light of the findings.

Example 2

A market was identified for a low cost pump to drive a mattress overlay and technology development in the latter stages. Design input was to present design concepts for the case of the pump. Some input continued during development. The final design was modelled by the R&D office on a 3D CAD package.

Example 3

The control of the front end of a major project with industrial designer involvement was expected to continue through the whole product development process. Input was provided on issues such as user needs, human factors and styling.

A more general activity of industrial designers involves assessing the potential for common solutions for selected products from across the division in terms of material technology, manufacturing processes and assessing the possibility of modularity between these products in service.

The group industrial designer is used strategically across the divisions joining their project teams. External design consultants are also used on new product development.

8.5 New product development

In Luton, Huntleigh Healthcare normally works on 10 new products at a time and introduces 4 to 5 new products a year. Ideally, new product development takes about one year on average but this can vary according to the complexity of the product (Daughtery, 1997).

In the past, there was a lack of coordination between the development and the production teams because the development period was a lot faster and prototypes were built up in the lab but only a few of them were working models. Nowadays, the company is trying to coordinate the departments more by implementing a more efficient process, so that the development team develops a product which can be taken in stages down to production; in effect where both teams work in parallel, rather than each team working in finished blocks.

Furthermore, the company realises that, in the past, product development was cost driven but now it is no longer good enough to put costs down on production and get away with high margins, since the present day market no longer allows such high profit margins. Daughtery said,

So we are now looking at getting the development team and the production team to work much more closely together - true development teamwork - so production engineers and quality engineers have to be in almost from the idea stage. As soon as we have an idea of how that product's going to look then they have got to be in looking at how it is going to be manufactured.

8.5.1 Ideal goals for new product development

Daughtery (1997) stated that when designing products towards the home care market the ideal goal is simplicity of use:

Our ideal product would be one where it had no controls, nothing else, and a box. You simply plugged it in, switched it on and it worked for any patient, and it automatically sensed what patient was on the product and adjusted itself, accordingly, etc.

The reason for this is that, in a hospital environment, people would expect a carer to come and regularly check the patient, but in home care people tend to be left almost alone. Therefore, the product needs to cope with less carer intervention because often there will not be a carer in the home environment.

Daughtery explained,

We do try to keep our products as simple as possible. We do base ours on various assumptions that we try to test out here, for instance, equipment setup in relation to the patient's weight.

Now we know that on our kind of product weight is not necessarily a true guide because you could have a very heavy person or a very thin person and then they would need a much higher pressure than a person of a similar weight who was extremely fat and wide, but when it comes down to any other kind of thing that you could try to put into the pump like body mass index, the average home care user simply isn't going to understand that and neither are the nurses in the hospitals, so we try to design things for a very simple interface wherever we can.

Daughtery (1997) observed that there is not much differentiation between the hospital market and home care market. The company tends to design the products more based towards the hospital market and the products naturally go into the home care market, usually via the route of outpatient clinics, doctors, or the social services.

8.5.2 Design strategy

In the company, there is no group design strategy as such, besides quality control and design control (based on Hollins and Pugh, 1990). Each division has its own targets to meet in terms of growth, and product design has to contribute to that. These margins are set for each division and for each product within each division. The percentage of growth assigned to a product must be achieved through target margins. Product concepts will stand or fall on their ability to achieve this. Any new product must generally follow existing routes to market (Harding, 1998b).

8.5.3 The role of design

The role of design is to contribute to the corporate objectives. The group will invest in research and development in order to keep ahead in the technology race and hence the market places. Harding (1998b) stated,

The group will strive to produce the highest quality products in the most cost efficient way, ensuring that the product and services we offer will present the most cost effective solution to our customers.

8.5.4 Ideas

Daughtery stated that people in the health-care industry are actually saying what they want and what they do not like; but they find it very difficult to come up with a concept

of what they would ideally like.

Therefore, to compensate for this, the role of the industrial designer at Huntleigh Healthcare includes coming up with numerous concepts that the marketing department will find beneficial and then showing those ideas and getting comment on them. Daughtery explained,

If a marketing team gives people a blank sheet of paper they are not very good at responding back. Quite rightly so, because they are not engineers, they find it difficult to get their ideas across.

The company tend to organise a focus group to get a concept of basic marketing facts such as what kind of features people want in a product, what price they would expect to pay, what patients they would expect to treat on particular kinds of mattresses, how many patients they would want to use on them, etc. From then they would - if they decided to go through with a product - put it into the system through a few ideas and perhaps develop a few prototypes.

At that stage, ideally, a marketing team would take these prototypes back and try and get some more focus groups organised, and show these groups what the company is doing with similar people. The aim is to ascertain if the design departments ideas are an indication of what users expect or if the company is deviating from what might be required.

In fact, the above is an ideal concept that the company would follow. But forming focus groups is very time consuming, and often people do not want to take the time out to be involved. Daughtery said,

A lot of the time we tend to do it (develop a product) on the fact that we understand what the market needs are. Our products are fairly simple, so once we've got some initial feedback and we've done a design specification we tend to try to stick with that design specification and we would push that down to almost a finished product.

At the finished product stage, user preference trials are held at which the products are evaluated to see if they are good enough for people to use out in the field. The company puts a selection of products out for real users to use in selected hospitals and effective feedback is then obtained. That feedback is then assessed to check that the product is suitable for the market that the company is aiming towards.

8.6 New product development process

8.6.1 Project management culture

The programme manager is in charge of all project work, which goes through him. His role is to make sure to prioritise projects and launch the products into the market place on time. One important task is to review the new product development process (Henderson, 1997). The route that Huntleigh Healthcare is aiming for is to create a project management culture. A project manager is in charge of a team of individuals drawn from all the required departments across the company. However, the project managers also have other job responsibilities. The main problem is the balancing act between their day to day work and their project jobs; the same goes for all the people within the project teams. Project managers also have other responsibilities in the daily management of the business and that obviously presents quite a number of problems in terms of priorities (Henderson, 1997).

8.6.2 New product development process

There is a well established document in Huntleigh Healthcare called 'New product development process' which is intended to give a comprehensive view of the project stages towards which continued development and design work is to be controlled. The reason for the necessity of this document is to ensure the long term success of the company, and provide awareness of legislation, i.e. FDA (Food and Drug Administration) & MDD (Medical Devices Directive), and ISO (the International Organisation for Standardisation) 9000 Accreditation. In the USA the principle legislative body is the FDA, and within the EC it is the Medical Devices Directive. The normal business that Huntleigh Healthcare is involved in is covered by these agencies, so that ranges from the products through all the other sub-divisions of the company, even those that are supplying services such as rentals and other consumable equipment that may not be of their manufacture, etc. have to comply with the requirements of these agencies.

8.6.3 Regulatory matters

There are three regulatory areas, ISO 9001, ISO 9002 and GMP (Good Manufacturing Practice), which have an impact on the design process. Because of legal requirements, Huntleigh Healthcare has GMP approval, which is similar to ISO9002, covering

manufacturing. But within the new legislation if a company starts to produce equipment that has a therapeutic application rather than just a preventative nature it has to have its design processes controlled otherwise it will be audited by a third party. The company is also looking again for ISO 9001 accreditation, because that goes into the new design development area which the company had to look at when revamping its process to accommodate regulatory matters (Bentley, 1998).

8.6.4 Project review group

The project review group consists of 9 senior managers from the management team who have the most influence and responsibility for new product development. They are the managing director, sales director, manufacturing director, quality manager, marketing development manager, export sales manager, 2 technical managers- one at Luton and one at Cardiff - and the programme manager. The programme manager runs this group, chairs it and organises the meetings. They meet formally on a monthly basis to review monthly project reports, and also to review projects when they get to critical phases in their development and to address any issues in terms of priority, financing or just finding ways around problems that have not been resolved elsewhere in the company (Henderson, 1997).

The programme manager acts as a conduit between the project management group and the actual teams. There are 8 project managers who have been trained for this role. They have programme teams under them. A number of people will be running more than one project. Most of the project managers report directly to people in this project management group. There is a lot of feedback both vertically and horizontally between various project management groups. The programme manager also runs a meeting with all the project managers each month with a view to focusing on improving the product development process. Henderson (1997) said,

I don't come from a medical company background. Quite a number of people doing project management have other backgrounds so it's trying to get this project management culture - reviewing how we do things, sharing experiences. A lot of what we do isn't breaking new ground, it's reiterating existing products.

According to Henderson (1997) for the stages of product development, project stages- a phase gate type scenario, there are number of stages which follow in sequential order thus

providing minimal commercial risk, and gives the least risk management route. However, on certain occasions, the time to market can be the key to success, and one way of shortening the time to market is to try and involve concurrent engineering practices and simultaneous engineering.

He stated,

You increase the risk, because you're doing things prior to certain items having been finished so Risk Management is important. So what we recognised is that we want do something quickly. We should declare that intention up front so it's planned in, and it's not as a reaction to the consequences of slippage or other problems. Because if you set these sort of scenarios then you're always going to have problems because you're not focusing on the key issues.

8.6.5 Project stages

'The new product development' is the project manual. This gives an outline of the procedures and cross-references to other documents and other forms, and is broken down into two parts. One part is called 'new product assessment' which covers idea screening, the initial assessment stage and the detailed assessment stage (see Figure 8-4). The other is called 'development of new Huntleigh Healthcare products' which covers the manufactured goods route, design development stage, process development stage, pre-production stage and launch/ product acceptance stage (New product assessment, 1997).

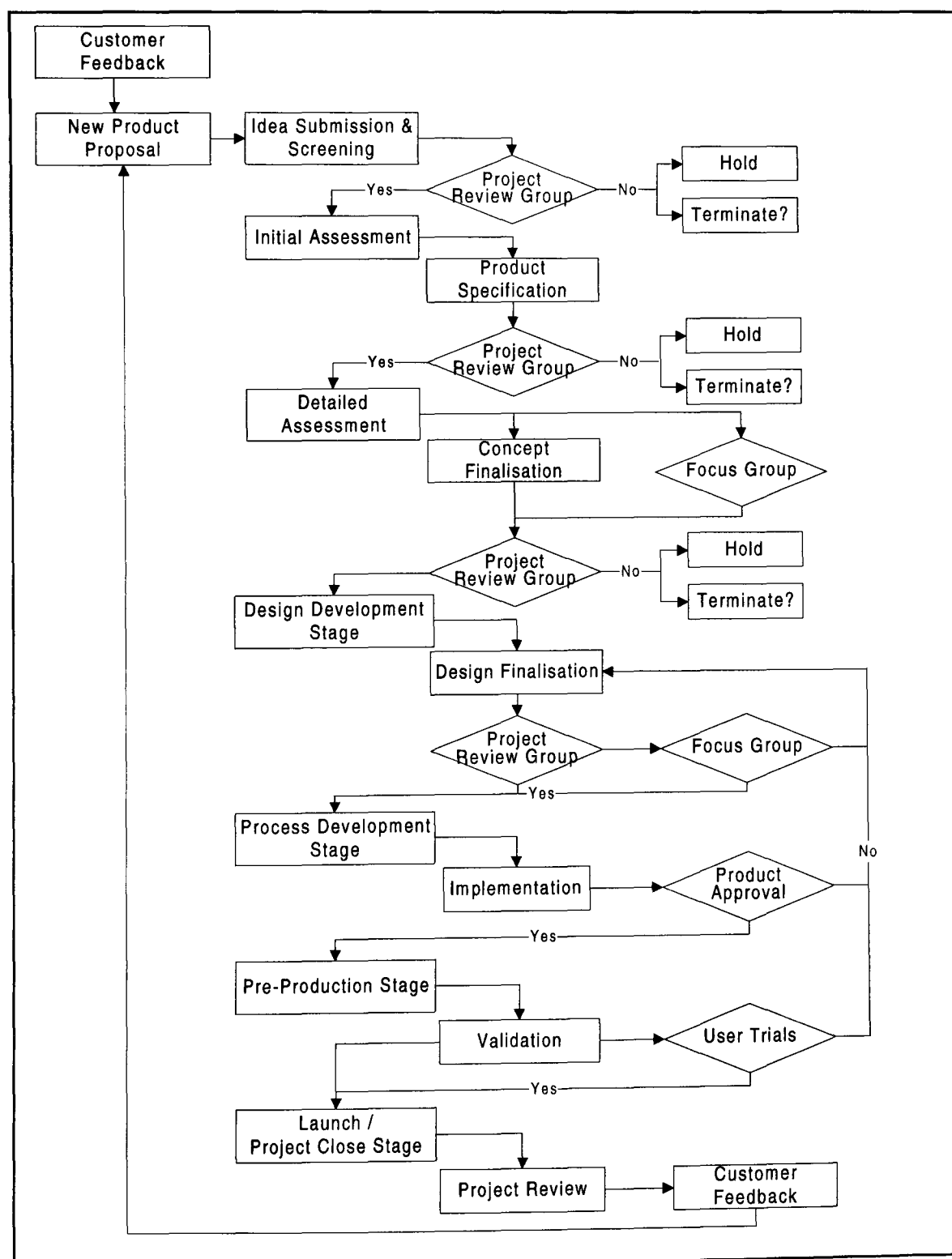
These are general development procedures but the project is obliged to follow these procedures according to ISO accreditation. The new product development process gives each stage a title that describes what needs to be done. So the first stage is the generation of an idea and a quick screening. The next stage is an initial assessment of that. Then follows the more detailed assessment, at which stage a project member should know exactly what they want, why they want it, and then start to implement it.

Huntleigh Healthcare uses two distinct routes in the way their products are developed, viz., the manufactured goods route and the factored goods route. The manufactured goods route is where the company has designed and developed a product in-house and is manufacturing it within the organisation. The factored goods route is a licence agreement or where someone is approached with an idea that the company has semi developed and they would like to find a sponsor to manufacture it. Another example of this route is

when Huntleigh Healthcare have an idea but they do not have the processes in-house to develop it, so it looks for a partner to develop the product, and then Huntleigh Healthcare can turn out it as factored because actual production will take place off-site.

The design process at Huntleigh Healthcare involves 7 major stages, viz., the idea submission and screening stages, initial assessment, detailed assessment, design development stage, process development stage, pre-production stage and launch and project close stages. These 8 stages are explained in more detail in the following sub-sections.

Figure 8-4. Design procedure - design process at Huntleigh Healthcare
(Constructed by S.Y. Lee-Interview at Huntleigh Healthcare with Mr. Henderson)



8.6.5.1 *Idea/ screening stage*

The first stage of the design process is the idea screening and submission. The intention is to encourage and provide a quick and easy way of raising and screening new proposals. New proposals are drafted on two sides of A4 paper. The first side of this sheet is filled in by the person with the idea. There are number of tick boxes, then a number of boxes with prompts in them such as 'why needed', 'when needed', 'customer benefits and Huntleigh benefit', so that these can be filled in. It is then submitted to the technical manager who then fills in the other side of this sheet. There are a number of commitments such as 'initial assessment commitment' and 'fast track commitment' which need to be filled in (see Appendix 5). It is then submitted to the project review group at one of the monthly meetings. The group will decide on the proposal and if they agree to review it they assign a project number to it so they can book some resources against it and prioritise it.

8.6.5.2 *Initial assessment stage*

The purpose of an initial assessment is to give a quick 'ball park' review of the technical and marketing viability of the proposal. It is undertaken within limited time scales and provides information for a decision on whether or not to carry the concept forward for detailed assessment and possible inclusion in the project portfolio.

This stage deals with looking at concepts of how the company can meet that requirement and validity. The assessment team review the proposed idea and develop a draft outline, called the 'Product Specification'. Next, the team determine the options in meeting the specification. These could be variations in designs, manufacturing techniques and supply, etc.

This assessment is then presented to the programme manager. At this stage, if it is accepted it gets given a Huntleigh Medical Project Number. From this point it is fully traceable under ISO systems. The programme manager and the individual department managers select a project manager from those who are training up and team members are picked to provide support.

Quite often the result is that the idea does fit but the company does not have the time and human resources available so the proposal is put on hold until a more suitable moment. If a proposal does not fit Huntleigh Healthcare requirements but it may fit within one of the other group companies it might be passed on there or, in the case of a proposal being unfit for what the company wants to do, the project is killed off.

8.6.5.3 Detailed assessment stage

The purpose of this stage is to provide detailed assessment and information for a decision to be made on whether to carry the concept forward with a selected desired option.

The project team develop the options left after the initial assessment by means of marketing analysis, technical assessment and financial assessment. If the project is viable or if there is a strong marketing case, this stage seeks to finalise product and project specification, produce a project plan, establish resource and project estimates and conduct a design review.

During this stage a concept is taken and is turned into a reality. The project team makes full use of CAD tools and some sketches and drawings. By the end of this stage, prototypes are made and tested to confirm that the design meets requirements.

The design that is evolved aims to suit customer requirements, at the lowest possible cost so that the company can produce to give the greatest flexibility.

The project team sorts out all the materials sourcing, components suppliers, tooling suppliers and how much it is going to cost. They then present this to the project review group, thereby allowing progress to the next stage.

8.6.5.4 Design development stage

The intention at this stage is to develop the finalised and verified product design with all of its associated documentation. This stage is broken down into two distinct parts, viz., design planning and design development.

The design planning process

The outline 'design management strategy' would have been determined and agreed with the project review group at the detailed assessment stage. In this design planning process

stage it would have been vital to develop the design strategy in detail and to identify and plan all the required design activities. The technical manager nominates a lead engineer to develop and determine the design activities.

The design development process

The design engineers hold a formal meeting with the manufacturing director and the quality assurance manager to determine the 'make or buy' strategy for components and sub-assemblies manufacturing and quality requirements. The designer produces a detailed design which meets the product specification and also reviews existing products problems.

The design development stage goes from a concept to a finished design with issued drawings, purchase specifications, structures of materials, and a level of having to justify what the engineers are developing.

8.6.5.5 Process development stage

The intention is to develop the finalised product manufacturing and quality processes with all of their associated documentation.

At this stage the necessary tools and materials are ordered and training programmes are initiated. Then the tools are brought in, and they are approved. Parts and equipment are also brought in and what is termed as a 'pilot build' takes place. By the time this pilot build is reached not only has the project team got the drawings and parts lists, but also the building, packaging, and test instructions, as well as work practices.

By the end of this stage all the tooling will be in place. This tooling will have all been approved and paid for, parts on the tools will have been made and tested and all the final drawings will have been completed.

All the process documentation, computer systems and order scheduling and everything else required will be ready for the following pre-production stage.

8.6.5.6 Pre-production stage

The purpose of this stage is to determine if the new product can be manufactured consistently i.e. correctly and within certain expectations, e.g., time, resources, price, etc.

Therefore, the manufacturing, inspection and testing processes will be validated as well as the design of the product during this stage for these aspects.

The project team at this stage do a systems trial run. They make sure they plan in batches that are representative of the batches that are intended for production. The production team run at least three of these batches through without the project team being there; the team just have a watching brief to be there to help it all happen. So during this stage, the production team will make up to 3 batches of items. A lot depends on production volumes and costing. Providing that this stage does not throw up any problems, the product from here could actually be used by end customers for demonstration, exhibitions, trials, and even perhaps for sale, depending on the novelty and risk that there may be clinically within that.

By the end of this stage, everything will have to be in place to support the sales and marketing of the product, so again final proofs of all literature and other bits and pieces will be pooled together. Also at this stage, the product will be used for final third party testing and validation. Sometimes the products could be used from the previous stage. They will have come off the tooling and products will be representative of the process.

8.6.5.7 Launch/ product acceptance stage

The purpose of this stage is to launch the product into the market place as planned. However, once launched, the project will stay live for a determined period so that products performance can be monitored before the project is completely reviewed and closed off, if acceptable.

The product is delivered to the market by means of a launch. Volume manufacture is initiated under the manufacturing production scheduling system. Everything is run by the manufacturing and sales organisation. Then the product is launched on to the market. A decision is sometime between three to six months after the launch to look to closing the project off and disbanding the team. At this stage, the project team is being looked to, to make sure that all the documented evidence is in place to satisfy legal requirements, that the product has met all the design requirements and that those requirements which were put down are the ones that were wanted.

8.7 Case Study: Micro Pump

This case study look at the development of a Huntleigh Healthcare product, the Micro Pump, which is a pump for the bubble pad mattress system and designed as a cheaper cost replacement of Huntleigh Healthcare’s existing products, called Alphabed and Alphacare. All three products are made for the overseas market. The Micro Pump, Alphabed and Alphacare use the same bubble pad mattress which goes on top of an existing mattress and it inflates and deflates by the air pump. The Micro Pump is used by low risk patients. It consists of two parts which are the bubble-pad mattress and a pump.

Product explanation

The pump supplies compressed air to a bubble pad mattress (see Figure 8-8), comprising two sets of inter-linked cells, inflating and deflating each set on a 10 minute cycle and during the alternating each set helps the blood circulation.

It was originally proposed to have three variants of the Micro Pump. A very low cost (VLC), which would be the simplest of the products, a low cost (LC), which would have a few more options, and a cost option (Cost), which would have even more features.

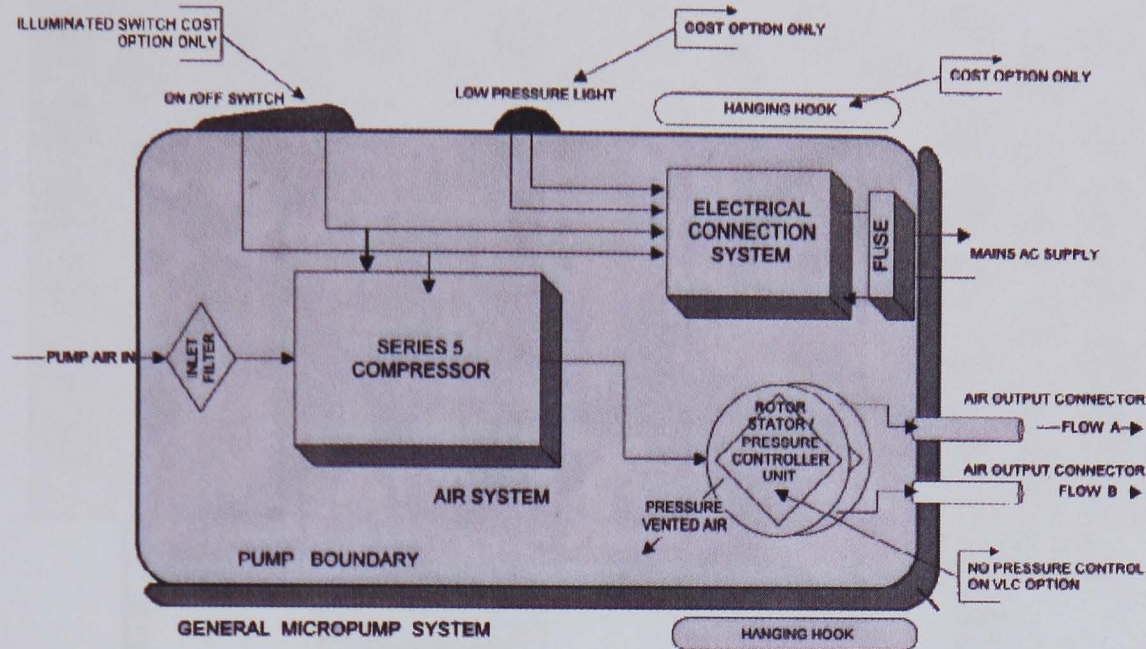
Feature	VLC	LC	Cost
Pressure control	No	Yes	Yes
Low pressure light/ indicator	No	No	Yes
On/off switch	Yes	Yes	Yes
Fuse	Yes	Yes	Yes
Hanging hook	No	Yes	Yes
Etc.			

Table 8-2. Features of products
(Source: Micro Pump project &product specification)

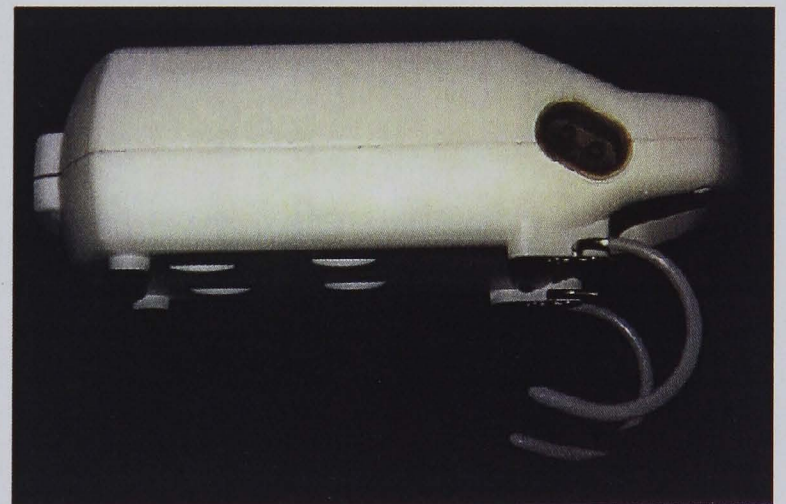
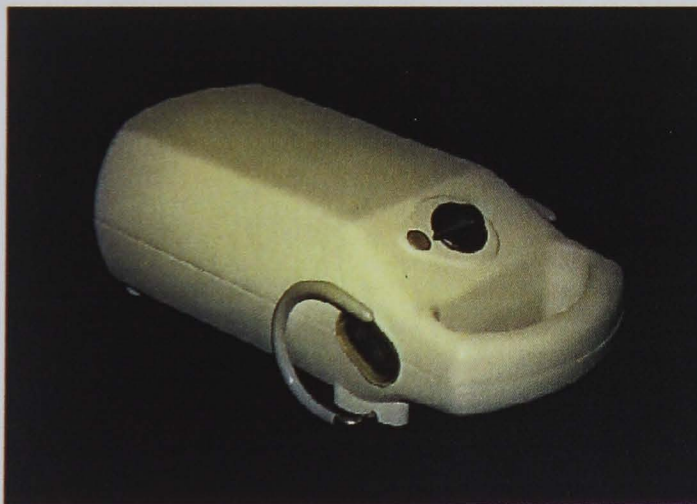
Pump

The Micro Pump is a push-on tube connection, with one power switch, a low pressure warning light and a pressure control. The pressure control is decided by the patient’s weight, fixed pressure at 85mmHg or optional rotary pressure control 30-85mmHg nominal.

It takes about 10 minutes to inflate but there are two rolls so one set of bubbles comes up and the other set stays flat and the rolls will alternate between the two sets over a period of time. If somebody is alone in a room at night the pump sound is slightly noisy.

Figure 8-5. Micro pump schematic diagram (1997)

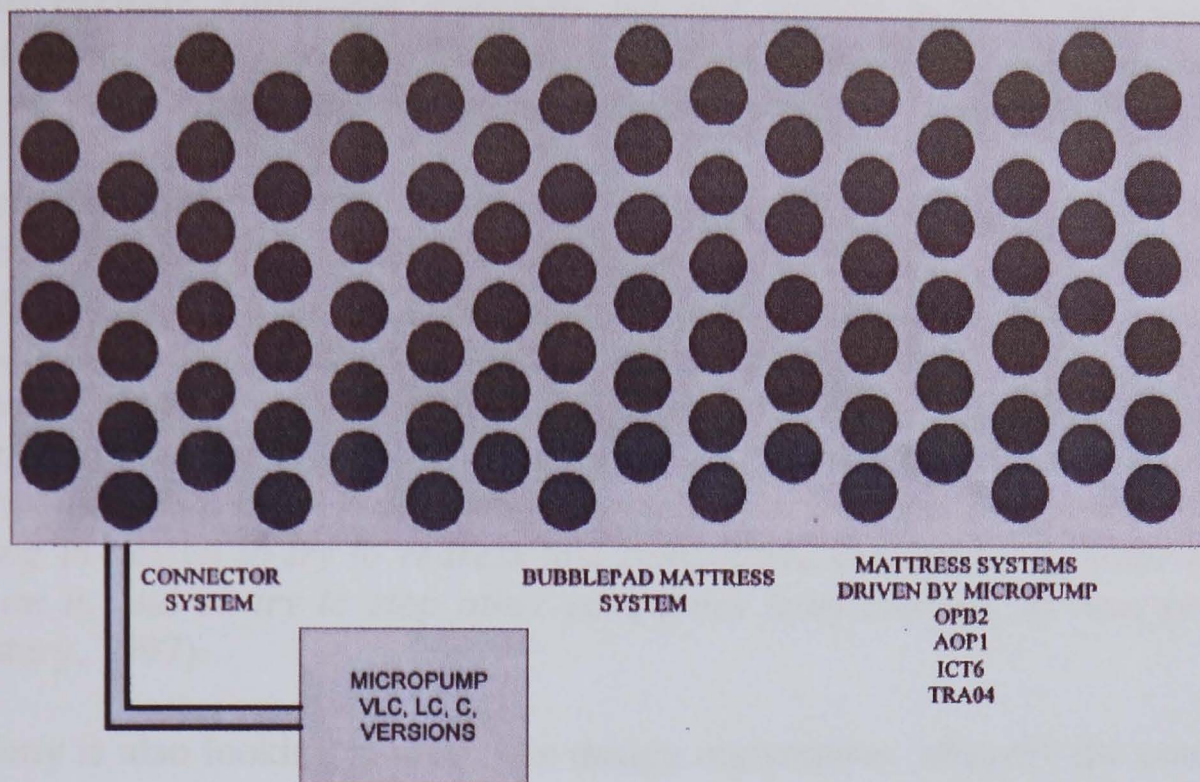
THE GENERAL MICROPUMP SYSTEM COVERS
THREE VARIANTS : >
VERY LOW COST (VLC)
LOW COST (LC)
COST (C)

Figure 8-6. Micro pump (Size: 300mm×130mm×100mm)

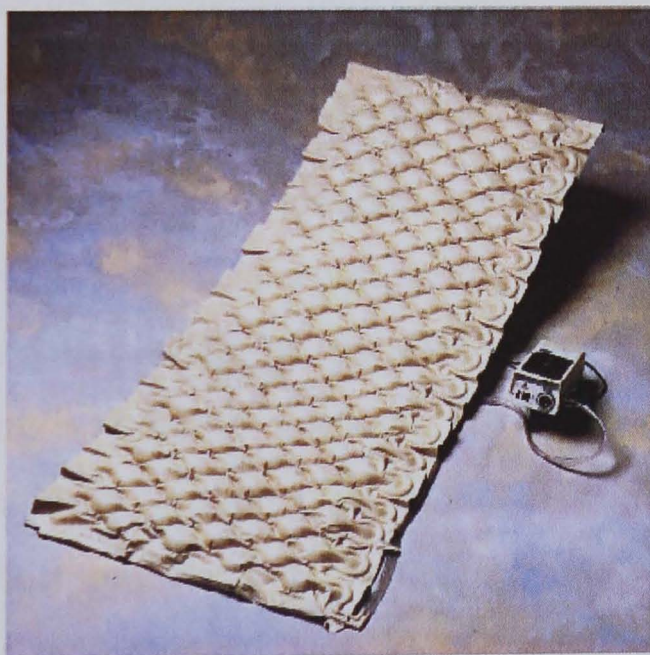
Bubble pad

Home divans can be quite uncomfortable to use all day so a simple overlay goes on top to reduce the pressure, and this is called the standard bubble pad. There are several versions of the pad. There is one that is made out of a thinner material which is designed for single use, is very low cost and is then thrown away. Then there is a more robust version which is for long-term use or can be re-used for several patients. It is of a slightly thicker material.

Figure 8-7. General micro pump/ Mattress system diagram (1997)



**Figure 8-8. Alphabed and overlay bubble pad system
(Source: Alphabed leaflet, 1996)**



8.7.1 Reasons for modifications

The low cost Alternating Pressure Air Mattress (APAM) market has become increasingly competitive over the past few years. A low cost product was needed to compete directly on price with the Taiwanese system, thus enabling Huntleigh Healthcare to regain sector market share and thereby slow growth potential of the low cost competitors. Daughtery explained

There is a Taiwanese based firm which is a 'copycat' firm which took and copied exactly the same pump as Huntleigh Healthcare's existing one but for a fraction of the costs because Taiwanese materials are not subject to VAT, and taxes and labour costs are very low, etc. Therefore, to achieve the above objectives the pump needed very low sales prices and manufacturing costs.

'So such companies came in and sold a 'copycat' product against Huntleigh Healthcare's existing product. Huntleigh Healthcare tend to get patents but such products are so much in the public domain it is very difficult to get a patent on them. So Huntleigh Healthcare tried to get a patent on the interior components. The law in Taiwan is not very effective on patent protection, but it does help protect Huntleigh Healthcare in own home markets. In the past, patents have expired, so the company does a lot of redesigning. In fact, redesigning is sometimes a factor it is putting in design to try to redress this competitive inequality, in order to get a patent on it, and so try to stop other companies from copying its own products' (Daughtery, 1997).

The company is also looking at areas like design registration, whereby the company will make a design similar to one of its existing products and try to register the design to stop direct copies. The competitive situation is so extreme that other companies copy many of Huntleigh Healthcare's products and sell them telling customers they are manufacturing for Huntleigh Healthcare under licence, which is not the case. Such tactics are used in such a competitive market.

If Huntleigh Healthcare lose this low cost segment of the home care market then most of these rival firms will become stronger and slowly start to come up behind Huntleigh Healthcare and erode, in time, Huntleigh Healthcare's bigger products. So Huntleigh Healthcare is trying to develop a pump for much lower manufacturing costs. Although this is not always possible, an example is the bubble pad itself, where the material cannot be bought in any cheaper. But, as regards the pump, Huntleigh Healthcare is trying to produce it at a reduced cost, for under half of the existing product price they currently manufacture it (Daughtery, 1997).

Who is the product aimed at?

These products are primarily aimed at the very low cost conscious markets (segments). In the USA in general, the characteristics of this type of segment is that it is driven by reimbursement and often sales go through an extensive distribution network (i.e. dealers). Additionally, the product is used in a homecare environment, whereby the product is

prescribed by a carer and the patient, or family member, will go to a dealer to purchase the product and then the patient or family member is reimbursed (Kemp, 1997).

Project team for the Micro Pump

The project team members are properly formed during the initial assessment stage. The number of the team members depends on the size of the project and are drawn from each of the main functions within the company.

At the idea screening stage, people tended to be drawn from the project review group or other senior people within their departments. At this stage, decisions were made by the marketing manager, project manager, group technical director and a member of the technical department. These people also considered future strategies for the Micro Pump.

For the initial assessment stage, the assessment team was made up of the project team and a sub-team of other members who were involved in testing only at this stage. In this stage, there was a project manager, a designer and a member each from quality engineering, purchasing, marketing and production engineering. These people formed the core project team which stayed until the launch (see Table 8-3).

Product specification

The project and product specification included all the information from marketing, engineering and manufacturing etc., such as customer requirements and marketing issues, manufacturing and testing, quality procedures, function requirements, environmental issues, regulatory issues.

Each member of the project team supplied their information to support the specification. They circulated the specification and put their comments on the draft copy. The project manager put all the information together and the management team approved this specification (see Table 8-3, Examples of procedure requirements).

<i>Stages</i>	<i>Activities</i>
<i>Idea screening</i>	<ul style="list-style-type: none"> • The initial proposal came from the managing director and he handed it over to the marketing department and engineering department. He identified main market niches etc. and was very much involved with the marketing department. The marketing department put forward some proposals outlining what engineering solutions were needed. • The project team provided some engineering solutions, and they planned the project with timescales, an initial budget, etc. • The project manager gave a presentation to the product review group (PRG) outlining how the project was going, what risks were involved, budgets, costs, etc.
<i>Initial assessment</i>	<ul style="list-style-type: none"> • The project team produced 'product specification' and they identified whether the developed five concepts worked or not., they also made some very basic prototypes and finally tested them. • They looked at engineering solutions and costings to justify if they could reach the target costs. • The project manager had a team meeting every 2 weeks at this stage. • The project team gave a presentation to the Product Review Group (PRG).
<i>Detailed assessment</i>	<ul style="list-style-type: none"> • The senior manager group chose a concept. • The project team prepared detailed designs such as putting dimensions, getting tooling costs, testing, providing detailed prototypes and carrying out validation testing. • Early on in this stage, one concept had been rejected because of technical trouble. The project team chose another concept which was known technologically and which covered previous technical trouble. • The team issued a production specification, product plan, financial assessment - costs, return margins, estimates, FMEA procedures, risk analysis which is a requirement of the medical Device Directive, etc. • They went through a design review with the quality manager, technical manager, production manager and assessed the product in detail.
<i>Design development</i>	<ul style="list-style-type: none"> • The project team verified and finalised the project plans such as mouldings, welding parts, a compressor and variance mouldings. They estimated the period of time as such, on average 10 weeks to develop a design, 15 weeks to develop and test it, 17weeks to get the prototypes together. • At the end of this stage, the project team had detailed component drawings which were sent to toolmakers and manufacturers and these produced parts for assembly. The company build a production line with all necessary quality procedures built into it.

Table 8-3. Examples of procedure requirements
(Source: Interview with Mr. Kemp)

Involvement of an industrial designer

At the initial assessment stage, the team identified the specifications. To a certain extent how the company reach the goals of specification is up to the design department. The industrial designer explained an outline of the features for the machine according to the design proposal and initial specification. He brainstormed with design engineers to get some ideas. After that he came back with several different drawings and concepts. The concepts are very much driven by what the company can achieve, and it normally focuses on low cost engineering-wise concepts. Kemp (1997), Project Manager, explained

We will go through the usual engineering procedures. From a senior management point of view, they are not too worried how we achieve this as long as we achieve the costs and the functionality of it.

The team produced a prototype of the pump with features positioned where they could be easily produced and where the internal components of the pump were located for ease of manufacture and packaging. The team aimed to identify a look which was achievable according to the design concepts.

Marketing strategies

Huntleigh's overall strategy is to position itself and its name as a high price, high quality supplier with substantial service back-up. Tactically, however, it is of vital importance to protect this end of the market and not to allow the competition to grow stronger and move upwards. Additionally, it is unlikely that selling solely through the existing distribution network would not bring the volume to obtain a market lead (Harding, 1998a).

One marketing strategy would be to trade under a different name since this could give the company the advantage that customers will not associate the Huntleigh Healthcare name with low cost and thereby a perception of low quality products. It can also minimise any limiting factors when approaching dealers who, for example, sell competitive high end products or sell to other dealers than the ones the company has given exclusivity to.

Table 8-4. Historic and projected sales volumes
(Source: Micro Pump project & product specification)

	1994	1995	1996	1997	1998	1999	2000	2001
<i>Alpha Care</i>	8,311	6,111	4,725					
<i>Alphabed</i>	10,049	8,324	7,690	18,500	20,000	21,000	22,250	23,500
<i>Micro Pump</i>					30,000	40,000	45,000	50,000

The key objective in the sales of the new Micro Pump is to supply OEM (Original Equipment Manufacturer) to as many dealers as possible. Obviously, the success in achieving this will substantially determine the volume. Market research into existing dealer networks in Germany, USA and Italy may substantially assist in the success of acquiring OEM's.

Therefore, the key strategy is to trade under a different name, focus on OEM deals with distributors and be priced competitively (Kemp, 1997).

Overseas market

In the USA the sale of healthcare products comes under a 'reimbursement code' so that these products go through a state aid system. If, for example, somebody needs a home care product, their doctor will recommend having one and, in effect, write a prescription that can be taken to a dealer. The dealer will supply the product to the customer free of charge but will charge the government. The problem is that the government pay a fixed amount, for example \$600 or \$1000, so the dealer has to match the system so he will get the cheapest product that matches the code. His primary concern is not about functionality and quality. He is interested in is the cheapest product. Such a situation makes it very awkward for Huntleigh Healthcare to actually manufacture the interface for the Micro Pump because the user does not actually have any say in the matter of buying it. The dealer is driven purely by financial concerns. Reliability is important to him, but functionality is not a priority as far as he is concerned. It is seen as somebody else's problem. He just wants to match the code, and for the product to be cheap and reliable (Daughtery, 1997).

Different foreign markets vary in their preference for the alternating procedures for the product specification of the Micro Pump. The Japanese prefer three rolls, so that two out of three can be alternated rather than the English version of preference of one roll alternating out of two. Various markets have their own preferences, but a 10 minute cycle is a very common and has been proved clinically to work quite well. The Turkish and Italian markets are so driven by price that they want the most basic system. They are not bothered about pressure control, as long as the product can push up to maximum pressure and two rolls alternating are considered good enough for their particular market (Daughtery, 1997).

These differences in requirements are often based on clinical training. In the UK market, clinical training is actually quite sophisticated. Huntleigh Healthcare do not provide a lot of this training, but they do have a clinical team, which tells people how pressure sores develop, what kind of product patients need to avoid, etc. Such a system of advice consequently generates business for the company 'through the loop'. But a lot of other foreign markets are not as sophisticated and a lot of people tend to stick with products they are already familiar with, disregarding new modifications and improvements, or are more cost led, and stay with a cheaper and, hence, very basic product (Kemp, 1997).

As a result, Huntleigh Healthcare has been forced to produce a variety of similar products to try to cater for as many of these different market requirements as possible, in order to maintain its own competitive edge.

General usage

Generally the Alphabed or Alphacare products are the equivalent to the Micro pump but are for use in hospital. These products, realistically, would only go under one or two patients at most before being thrown away. The product can not be cleaned since it does not have a cover. All the other products are more sophisticated having a polyurethane cover or stretch material, etc. With a simple product like the Alphabed or Alphacare it is not a problem if the patient soils the mattress since this can be cleaned with fluid. However, after a while, it has to be thrown away. Huntleigh Healthcare has various different outlets on these lower cost pumps and, depending on the country, some markets are extremely unsophisticated.

User studies will be undertaken by the company as soon as 'end product' representative samples are available. Samples and user study results will be channelled through the Marketing Department (Kemp, 1997).

The development of the Micro Pump aims to provide company benefits namely, to enable Huntleigh Healthcare, its subsidiaries and distributors to compete with cheap Taiwanese based products currently flooding the market, to protect margins and market position of existing Alphabed and Alphacare products, to revive and re-launch Huntleigh Healthcare as an all round PAC provider, and to generate additional revenue (Daughtery, 1997).

8.8 *Huntleigh Diagnostics (Cardiff)*

Huntleigh Diagnostics, based in Cardiff, is established for the design and manufacture of diagnostic ultrasound equipment for vascular and obstetric applications. Their products are the Dopplex range which are foetal monitoring systems for community and hospital use.

New products have been continuously added to the Dopplex range for both vascular and obstetric use in the last few years. Baby Dopplex 3000, a lower cost, antepartum foetal monitor was launched in 1994. In 1995, the company added instrumentation to the products resulting in the production of the BD 4000. These included the Q-Scan™ system, a non-invasive angiography and the Rheo Dopplex Doppler, a light reflective rheograph for arterial and venous flow assessment (HNE Technology plc Group Annual Report, 1997).

Huntleigh Diagnostics provides an electronic design and manufacturing service to other divisions within the Huntleigh Technology plc Group which is in compliance with national and international quality systems. In 1995, 140 people employed at the Cardiff site. In that same year, the company exported approximately 60% of output to Europe and the USA, with 40% of sales in the UK (HNE Technology plc Group Annual Report, 1996).

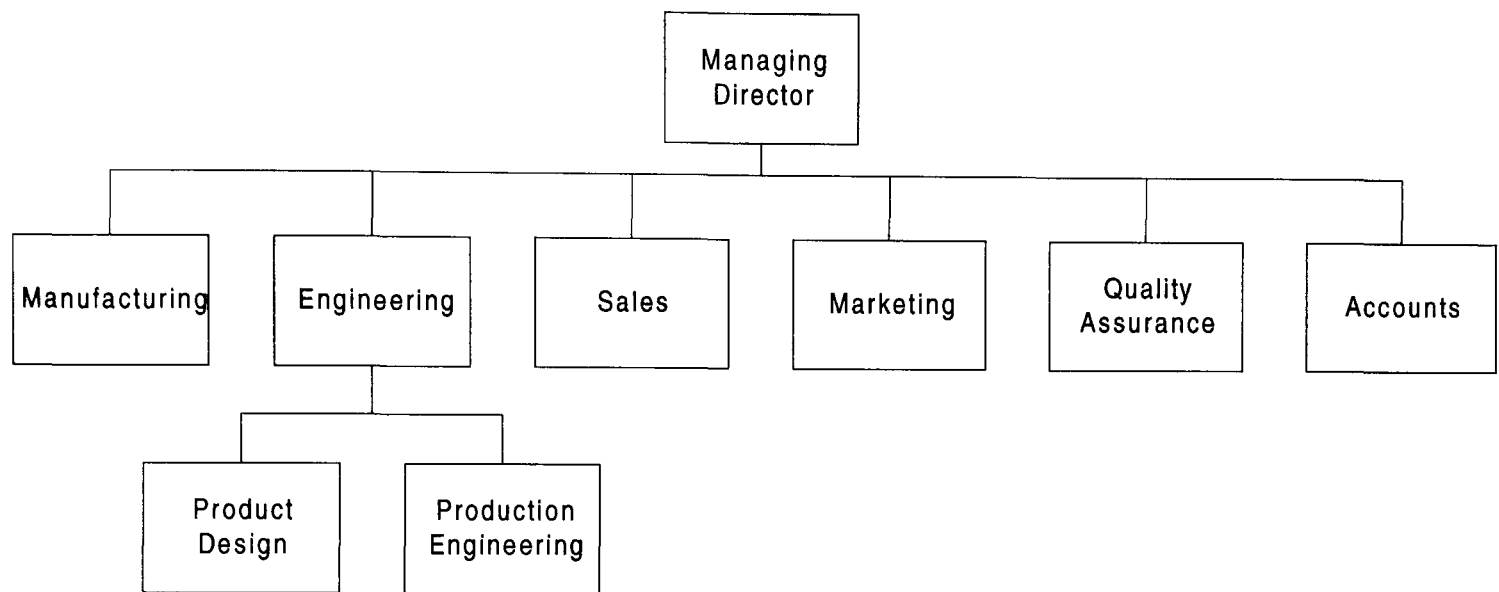
8.9 *Design Department*

Product design happens in the engineering department and this department consist of a number of electronics design engineers, mechanical designers, a few technicians and support staff. It also has production engineering and production support. The person in charge of the engineering department is the technical manager. The engineering department is split into two sections, viz., the product design and the production engineering sections (see Figure 8-9). Baily (1997), the Technical Manager, stated that the running of the engineering department is project based so they do not isolate specific functions like electronics, mechanical design or industrial design. These areas, in fact become part of the project.

Formerly there was one industrial designer employed at this site but in 1997 there was none. The department has a connection with the group industrial designer or an external consultant when it develops a new product at the beginning of the developing stage for the sketches and drawings, etc.

Once a product is approved, the development happens in the engineering department but this department also works quite closely with the manufacturing department at the various phases of production. Baily stated that what they try not to do is put sequential barriers between each area because certain sub assemblies might be ready for production earlier than others while the rest of the product is still being finished.

Figure 8-9. The organisational structure of Huntleigh Diagnostics (Cardiff)
(Source: Interview with Mr. Baily, 1997)



8.9.1 New product development

The Cardiff site typically introduces two or three new products a year, but in 1997, four new products were launched. To develop a new product normally takes 12 to 18 months but it depends how significant the product is. Normally a product survives in the market for around 5 years. During these 5 years it usually undergoes some modifications. Minor modifications occur for all sorts of reasons like component obsolescence. The company have made steady improvements of the products for function, reliability, cost, etc. (Baily, 1997).

8.9.2 Proposal of initial ideas

Baily said the ideas can come from anywhere and the new ideas can originate from a combination of different people, for example, from engineering staff or from the marketing people, or a collaborative effort from a variety of departments. If anyone wants to propose an idea for a new product the company tends to discuss ideas with each other. Even though the group encourages new product proposals, Baily stressed that the important element is to have effective communication and filling in forms is not essential.

8.9.3 Incentive policy

There is no incentive system for in-house people who propose ideas for new product development.

8.9.4 Decision making

When the company has a new product idea, this tends to be discussed at the senior management meetings. Baily stated that once a new product idea has obtained approval more work on it is carried out, both commercially and technically. At the Cardiff site, a formal management meeting occurs every month at which approval or rejection of a proposal idea is discussed.

There are also design review meetings. These meetings generally involve management representation plus the relevant project manager and whoever the project manager feels appropriate to bring in. Those are the more formal meetings. There are also design reviews with other meetings on a daily basis between team members.

8.9.5 Design brief

As part of the feasibility structure the company generate design briefs. In the past, these briefs occurred occasionally but now the process of generating such briefs is becoming more formalised, so that there is both a functional description of the idea and then following that, a more detailed design description.

8.9.6 Design strategy

There is no formal design strategy for this site but Baily said that, to some extent, for example, a marketing strategy exists in relation to market exploitation.

8.9.7 The role of design

Baily believes the role of design is to develop ideas, to innovate new ideas, to provide new applications and to work in conjunction with all the other departments in formulating them; furthermore, turn those ideas into physical reality within the constraints of product costs, development time frames and development costs, and then to put that into production.

The role of the engineering section is to support production in their normal activities, particularly if the company is changing supplier or if a component is made obsolete.

Baily expressed product design as one of the engineering section's responsibilities and design is only one part. He further said,

I guess when industrial designers talk about design they are talking from the angle of industrial design.

8.10 Case study: the Baby Dopplex 3000

The Baby Dopplex 3000, a lower cost antepartum foetal monitor, was launched 1994 and was intended mainly for community use, typically by a community midwife. Similar but higher specification equipment like the Dopplex 4000 machines were intended for sale into the hospital environment (see Figures 8-10 and 8-11).

The original product, the Baby Dopplex 3000, was intended to be low cost for the community practitioner and included only antepartum monitoring, that is, prior to the waters breaking. It provides foetal heart rate monitoring. The updated ranges of the Dopplex 4000 also include intrapartum monitoring of the foetus for tracking heart rate. It includes other features like foetal movement profiling for twins.

Figure 8-10. Baby Dopplex 3000
(Source: Huntleigh Diagnostics leaflet, 1994)



Figure 8-11. Baby Dopplex 4000
(Source: Huntleigh Diagnostics leaflet, 1994)



8.10.1 Reasons for modifications

In terms of competitive systems the base model of the Baby Dopplex 3000 only provided one application for this type of device. The reason for the modification was to extend the application areas. For instance, in hospital labour wards, intrapartum versions are always bought. Huntleigh Diagnostics did not previously have a product to monitor twins.

In this Baby Dopplex 3000 example, there is a fairly well established market and there is nothing particularly new about the application. What Huntleigh Diagnostics was trying to offer was something at a much lower cost to what was currently available. The company also tried to make a previous version of Baby Dopplex more compact and more aesthetically pleasing. All the existing units looked like engineering units, but Huntleigh Diagnostics tried to design it so that it was pleasing to the eye. Additionally, the user interface was mocked up quite early in the development, and the unit was tested with a number of potential users, and feedback was obtained to try to make it as simple to use as possible.

The results of the feedback showed that some of the devices on the market are quite complicated to set up and the features that can be set up are consequently not used. The devices which users ended up buying were bought on the basis of what had been bought a previous time. Users prefer to use the same features all the time rather than the full features which might be available in a more comprehensive product. So Huntleigh Diagnostics tried to make the Baby Dopplex 3000 much simple for users to set up and operate.

The Baby Dopplex 3000 is only suitable for antepartum use and the Baby Dopplex 4000 is used for antepartum and intrapartum and includes foetal movement profiling plus twins monitoring. The Dopplex 4000 has extra features which feedback showed were wanted by the users. So in terms of benefit, it is in expanding the application of this device to be more complete. The extra features are more expensive to manufacture and the cost is passed on to the purchasers.

The Dopplex 3000 took about 18 months, and the Dopplex 4000 took about 12 months for development. The reduced time span for the Dopplex 4000 was because there was no need to redesign all the injection mouldings and other features which had to be designed the first time round. Some new mouldings were used and were produced by electronic re-design, thereby, again, reducing the time-scale.

The company manufactures all products for hospitals or community use in general. They do not have any products for home-based health-care but Baily (1997) believes,

There will be more use of equipment in the home, in future; but not necessarily applied by the patient. It will be controlled, I think, by clinicians who will be devolved away from hospitals. If you put in diagnostic equipment for people, you need to be trained in order to interpret the data'.

8.11 Huntleigh Kinetics (Liverpool)

This division has over 60 years of historical background, and has a long tradition of supplying rehabilitation equipment for the elderly and disabled.

In 1978, the company called F. Llewellyn & Company Ltd started to manufacture a range of aids for disabled people, for example, commodes (a chair frame underneath which is a bucket slung under the frame for going to the toilet), manufacturing their own beds, overbed tables (where the legs are on castors to go under the bed and a tray which goes over the bed), bathing aids and kitchen aids (Morrissey, 1997).

In 1985 Llewellyn's combined with a company called SML and became Llewellyn SML. In 1989, they merged with a company called Nesbit Evans. Nesbit Evans, used to manufacture a range of side rails which were designed to fit onto the Llewellyn and Nesbit Evans range of beds for both hospital and home patients to stop them from falling out of bed. Nesbit Evans has now been taken over by Huntleigh, so they are now Huntleigh Nesbit Evans, but they trade as Huntleigh Kinetics because the company now specialise in kinetic equipment (lifting and handling) such as mobile patient lifting hoists, bath lifters, toilet risers, etc.

Huntleigh Kinetics operates totally separately. Huntleigh have historically been involved in pressure relief mattresses, etc. Morrissey(1997), Marketing Manager, believed that the idea of the merger with Nesbit Evans was because Nesbit Evans' strong line was in both hospital and community beds and they saw a tie up between pressure relief mattresses and the beds which they manufactured.

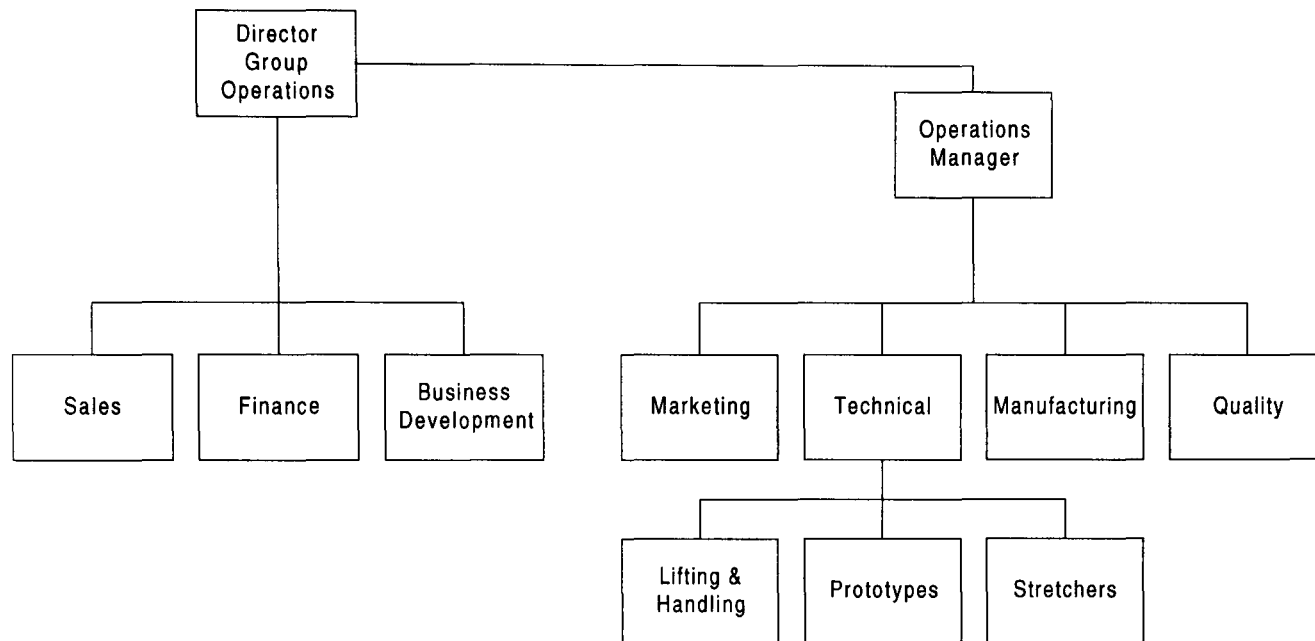
Huntleigh Kinetics' manufacturing activities centre on equipment to aid the lifting and handling of patients and in 1995 the Pisces bathlifter, Porta™ mobile hoist range and Quiet Riser™ powered back rest were launched.

Investment in quality control, product development, engineering and export initiatives has given Huntleigh Kinetics the resources to expand and develop its services to the non hospital sector in the United Kingdom and overseas.

The Director of Group Operations is based in Luton, with overall responsibility for the Liverpool site. Brooks was the Operations Manager in 1997. At that time, there were 96

people employed in this division. The company export 40% of its product overseas. Investment in quality control, product development, engineering and export initiatives has given Huntleigh Kinetics the resources to expand and develop its services to the non hospital sector in the United Kingdom and overseas (HNE Technology plc Group Annual Report, 1996).

Figure 8-12. The organisational structure of Huntleigh Kinetics (Liverpool)
(Source: Huntleigh Kinetics Structure, 1997)



8.12 Design department

The technical department is responsible for the design and development of new and modified products. It consists of 11 personnel made up of mechanical design engineers, electrical design engineers, detail design draftsmen and a technical manager who has overall charge.

Robertson (1997), the Detail Design Craftsman, explained that the team number increased in early 1997. The department is split into three sections, namely, lifting & handling, prototypes and stretchers sections (see Figure 8-12). The increase in personnel was due to business expansion and structural reorganising.

8.12.1 New product development

The Liverpool site normally introduces two or three new products a year which includes improvements and modifications. Once a new bathlifter, for example, is launched on the market it stays for 2 years at current trends and its life cycle becomes increasingly shorter because of competition and user demand for better quality products at a lower price.

Maximum sales of products from the Liverpool site normally exist for a year and then the sales start to drop off as competitors start to bring out better products.

If a particular product is not selling well, then another improved product is brought out. Otherwise, Westcott (1997) stated,

Because we have only a small development team and the industry that we are in is one very much where we see what our competitors are doing, our competitors see what we're doing and we try and reimprove on our own design. They improve on our design, we improve on theirs.

The company uses two main ways to develop new products and a third, less common, method. One method is that the designs are evolved from what is already in existence in the market. For example, if one of the competitors wanted the same goods or products then Huntleigh Kinetics would come up with a similar product but better again so as to obviously compete against them. That is one way the company starts a new design.

The second method is to obtain feedback from the marketing and sales departments. The marketing or sales people might comment, for example, that numerous customers have asked for a vertical rise with a motorised traction for a product. The company then decide if such a suggestion is feasible and if so it starts to build a prototype (Westcott, 1997).

An example of this second method is the evolution of the Pisces product. Marketing decided that they wanted to hit one particular section of the market and that was the upper end. They wanted a prestigious product which looked good and which was the obviously at the right price. Morrissey (1997) said that the market for the Pisces product had changed somewhat and it had not been as successful as they had anticipated. It was accepted that the main reason for the failure of this product, even though sales and marketing people obtained feedback from customers, was that the product had not been competitively priced in relation to other, similar products which were already on the market.

There is also, to a lesser extent, a third possible method of developing new products, namely, from ideas which can come up independently from the design team itself. In recent years that is how some designs have evolved.

New product development periods depend on how evolved the product already is. A completely new concept takes between 12 to 18 months and redesigning takes between 6 to 8 months.

8.12.2 Proposal of initial ideas

At the initial idea stage, a particular product or design can be generated from any source, but primarily from sales and marketing. They use a suggestions form which outlines the benefits to the company in terms of increased business or a new opportunity, the benefit to the customers and the pitfalls and risks.

The suggestions form has to be reviewed by the management of the development team, and then it has to be inserted into the new product development plan.

Assessment of a new product is linked to competitive rivalry. According to Morrissey (1997), when Huntleigh Kinetics come up with new ideas and design a new product it needs to be put into the market place for people to assess so as to obtain feedback. However, it is reluctant to do this because competitors would have forewarning that Huntleigh Kinetics is planning to bring out a new product, thereby allowing competitors a head-start on updating their rival existing products. Consequently, Huntleigh Kinetics does not put new products out to the general public to test.

Brooks said that if Huntleigh Kinetics develop a completely different product, although it might take a lot longer to develop, market opportunity is high because, once established, it can become a market leader. However, if similar products are already on the market another new product increases the competition.

8.12.3 Customer opinion feedback

The sales department brings in feedback from customers and the marketing department comes from the other end. Sales representatives go to the hospitals, do a demonstration and ask questions. Sales representatives get all the results in from all the sales people and discussions are held between marketing, sales and operations, and together decide which route will be taken.

Based on feedback results, Brooks said everyone wants a better looking and cheap product even though this may not be the best expectation. Sales volume which has been proved is based on the cost and functionality of a product as still being more important than the initial visual appearance of a design, although aesthetics, he concedes, has some effect. Huntleigh Kinetics can make an aesthetically pleasing product, such as adding

mouldings on a bathlifter product which could hide certain parts or components but this would not much add to the value of a product, only to its perception by the user. For example, regarding bathlifters in Japan, feedback was obtained by sales representatives going to Japan and talking with users and buyers. It was found that Japanese people wanted the bathlifters to go much higher because of plunge pools. They also wanted a design which was aesthetically in line with existing Japanese style. However, Huntleigh Kinetics decided not to carry out these functional and aesthetic modifications because marketing shows that sales volume would have been insufficient.

In short, the company has to ensure that the ideas that are put forward are primarily functional and economical.

8.12.4 Decision making

The final decision made by Brooks, the operation manager is to sign off the idea form for the next development stage. Brooks said, *'What we are saying basically is if we have an idea, how many could you sell and how much would they be?'* He further stated that the sales representatives make the ultimate decision regarding the feasibility of a new product, since they are responsible for selling it: *'At the end of the day if they can not sell it, they won't push it'*.

During the initial ideas stage and prototype stage, meetings are held once or twice a month, on a regular basis, to provide feedback on what progress has been made.

8.12.5 Design brief

Westcott said they do not have a design brief in place yet but he believes that design brief is in the form of a user requirement specification. In each case, in order to design, they have to do so against the user requirement specification.

He explained that their specifications go to great lengths to try and make sure that all aspects of requirements are covered. The specifications are in the form of two documents. One is a specification document and one is a verification regarding it. The first sets out all the constraints and the second deals with product needs and specifications.

8.12.6 The role of design

Brooks believes that the roles of design are to produce products that are within the required standards and legislation, are competitive and efficient, and that will allow design of the product within specifications.

Westcott said the role of design within product development is very much one of ideas and whatever the original concept for a product, the finished product should always satisfy user requirements. The concept comes in from the ideas form (see Appendix 5). The implications and the way that the product is developed from a concept or a sketch will be carried out by design. The concept would encompass the user requirement specification. In all cases the concept must go back to what the user needs. They recognise that they cannot simply satisfy just one area. Their users might not be the end user, it might be the local health authority. They are now looking at getting information right from the provider to the end user.

So it is the likes of the Muscular Dystrophy Group and the other support organisations, these people with different types of illnesses, that we speak to. We are actually working with these organisations to develop a product for that particular type of ailment (Westcott, 1997).

With certain illnesses such as multiple sclerosis or muscular dystrophy, Huntleigh Kinetics works with the agencies, and people who look after and represent the needs of the particular sufferers of these illnesses. When their requirements have been obtained Huntleigh Kinetics can design against these, but it is careful not to design specifically for one group. It must be adaptable enough to cater for the whole market.

8.12.7 Design strategy

The design strategy does not come from the design department itself but as result of feedback primarily from the sales and marketing departments.

8.12.8 Implementation

In the past new design was implemented through marketing but nowadays the sales department also provides feedback through the sales department and or from the marketing director. Brooks said the marketing team knows what products their

competitors are selling, how many they are selling and the profit margins they are looking at.

When the company implement a product they check the new product development form, to check whether or not they have completed the tasks. They decide whether or not it fulfils the product requirement. If it does fulfil this they then look at making the unit, but in the most cost effective way. It is important to ensure that the final agreed product is built in the most cost effective way. This maximises Huntleigh Kinetics' benefit:

We're in a business to make money. We must make any of our products at an economical cost because if we make them at an uneconomical cost our competitor will make them economically and we will be out of business (Westcott, 1997).

8.12.9 Regulatory matters

Westcott (1997) said that they had a lot of other commitments that they had to fulfil that year. For example, all of their products had to become accredited, the Medical Devices Directive and the quality system had to be brought up to the standard of ISO9000 which was their main target of that year. If any new products were introduced these also had to be approved by the Medical Device Directive and so Huntleigh Kinetics' development work was being concentrated on achieving that.

However, since Huntleigh Kinetics' design team is small, some of their designs had fallen behind. Other competitors had brought out new designs. Unless these devices were manufactured and designed in accordance with quality procedures and Medical Device Directive within a very short period of time they might find themselves having trouble exporting to the European Union.

8.13 Case study: Pisces

This case study looks at the development of Pisces bath lifters. The bath lifters are predominantly community care health products. Huntleigh Kinetics had several versions of bath lifters which were modified for several reasons. This study presents how and why they were changed.

8.13.1 Reasons for modifications

The company originally had a product called the Gemini (see Figure 8-13). They specified the product, the Leo (see Figure 8-14), and they got feedback from the Gemini outlining that what was wrong with it and what people disliked about it.

Figure 8-13. Gemini - Bath Lifter
(Source: Huntleigh Kinetics leaflet, 1997)



Figure 8-14. Leo - Bath Lifter
(Source: Huntleigh Kinetics leaflet, 1996)



Figure 8-15. Pisces - Bath Lifter
(Source: Huntleigh Kinetics leaflet, 1997)



This product basically works on a bag which is inflated with air through a compressor. The user puts the battery in, presses the button and a little compressor blows air into the bag. The bag inflates and lifts the seat. When the user wants it to go down, he or she presses the button and the air is expelled.

The company found that users considered this operation cumbersome. Feedback produced other dissatisfactions. Users had difficulty carrying the device, and it could not

be folded up, it was noisy and it was not considered aesthetically pleasing. Brooks (1997) found that nowadays looks are important:

Whereas in the early days I think they were just so glad to get a piece of equipment that would help but not now.

The company has competitors who produced a product which was much more pleasing to look at. Huntleigh Kinetics found that competitors' products were all very noisy as was the Gemini but, all in all, the competitors' products were nicer to look at and were also simpler to use.

8.13.2 Target market

The target market was dictated by the marketing department. They decided where there was a niche in the market where Huntleigh Kinetics could hit its competitors, and this turned out to be the up-market bath lifter. A lot of money was invested to produce a suitable tooling, to make it look the way it does.

8.13.3 Feedback

The company looked at the competition and looked at their own product and they got feedback from their previous purchasers of the Gemini; via their sales people, from the marketing department. The marketing people asked to change some parts that they thought would be better for winning that market.

The company did needs analysis and went through the system of designing the product to a specification. In total, this took 12 months. However, in the time it had taken to specify and re-design the Gemini the market had changed (Brooks, 1997).

Originally when the company specified the Pisces product the sales price was quite high. They were quite confident of achieving that price but by the time they launched it, the customers did not want it because of the price, even though functionally it was well liked. In short, Brooks stated that in the UK prices are important and looks are secondary, whereas in Europe looks are important and price is not so far behind.

8.14 Summary

HNE Technology plc Group's three manufacturing divisions, viz., Huntleigh Healthcare, Huntleigh Diagnostics and Huntleigh Kinetics have been involved in this case study, but they operate fairly autonomously.

At group level Huntleigh Healthcare has their own new product development procedure which has a formulised view of project stages. Currently, Huntleigh Healthcare leads in applying this procedure.

The design and development of new products is involved with the engineering department or technical department. Technical managers are responsible for each of these departments. The group technical director works towards unifying the divisional research and development (R&D) operations bringing each R&D division up to the same level of effectiveness as that of the Luton site, which leads at present. The group technical director has overall responsibility for each division's product development, and also has close relations with technical managers.

New ideas are gained from customer feedback and/or sales department and/or marketing department. All new ideas are submitted on a new product proposal form but there is no place for the users' needs or requirements. Each division obtains new ideas from different sources and each project is also treated differently.

The project review group consists of senior managers and they have most influence and responsibility for new product development but, in the case of Huntleigh Kinetics division, the sales department gives the strongest force for new product development. A project review group meeting is held formally on a monthly basis to review projects and each division organises this meeting by their own schedule. Meetings at the Cardiff and Liverpool sites also involve senior managers from Luton, for the example a group technical manager from Luton also attend these meetings. Therefore, a very close and inter linked responsibility exists.

Huntleigh claims the reasons for new product development or modifications depends on each project's requirement but in most of the cases in this study the main emphases for new product development were found to be, first, staying in advance of competition, with

products such as the Baby Dopplex 3000 of Huntleigh Diagnostics Cardiff and the Micro Pump of Huntleigh Healthcare Luton, or second, catching up with the market, with products such as Pisces of Huntleigh Kinetics Liverpool.

Furthermore, Huntleigh emphasise that they are very much concerned about customers; and users' opinions are fitted into the new product development process throughout a number of stages.

<i>Manufacturers</i>	<i>Stage I</i>	<i>Stage II</i>	<i>Stage III</i>	<i>Stage IV</i>
Huntleigh Healthcare	○	○	○	○
Huntleigh Kinetics	○			○
Huntleigh Diagnostics	○			○

Customers' opinions are obtained at a number of stages and converted in a number of ways. User trials can be inconclusive. For example, Huntleigh Healthcare does user studies or comfort trials of its products. The evaluation team cover up various Huntleigh Healthcare's products and other companies products with sheets. The testers move down three or four beds and rate the beds from the most comfortable to the most uncomfortable, etc. Generally 50% vote Huntleigh Healthcare's product as the most comfortable and 50% will say it is the most uncomfortable. So this proves that the perception of comfort is extremely subjective.

Huntleigh Diagnostics produces products for hospital or community use, such as foetal diagnostic products, but there is not such a difference in terms of new product development in comparison with the other divisions.

The managers recognise the importance of design but their understanding is quite different in terms of new product development. Most of them conceive design as a very small part of the overall activity, such as art oriented activity, the appearance of a product, or the aesthetic view of a product.

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Chapter 9

Arjo Ltd.

CHAPTER 9. ARJO LTD.

9.1 Introduction

This case study provides examples of the product development process in a multinational firm, Arjo Ltd. The relationship between the division and the parent headquarters and the product development within the division are discussed in Section 2. Section 3 discusses the design department, the proposal of initial ideas, customer opinion input, the incentive system, decision making, design briefs and design strategy. Section 4 covers product development procedures. Section 5 looks at the development of a product, the Sara 2000 a standing and raising aid product. The final section summarises the pattern of the new product development process in Arjo Ltd.

9.2 Arjo Ltd. in the Getinge Group

Arjo Ltd. is a manufacturing company of the Swedish group, Getinge Industries. Getinge Industries, which operates in the field of medical technology, develops, manufactures and markets equipment and systems for sterilisation and disinfection purposes within the pharmaceutical industry and health-care sector. Getinge also develops, manufactures and markets hygiene and patient handling systems for the care of elderly and disabled people in the health-care sector. Getinge is also involved in the distribution of equipment and disposable items to the dental sector in Scandinavia, health food products to Swedish health food stores, and surgical instruments to the health-care sector, as well as supplying Swedish hearing centres with equipment and services. The Group is one of the world 's leaders within all of the above sectors (Getinge Industries AB, Financial Statement, 1996).

At group level, the whole range of products involves with approximately 200 products. Arjo Ltd. in the UK manufactures patient handling equipment. The Group consists of 60 companies with around 2,700 employees in 21 countries, of whom 224 are employed at Arjo Ltd. in the UK. The Group achieved an annual turnover in 1995 of about £350m with approximately £40m for Arjo Ltd. in the UK (see Table 9-1).

Geographical Destination	Turnover(£'000)
Getinge Group	350,000
Arjo Ltd. (UK)	40,000
Total	390,000

Table 9-1. Turnover (source: Getinge Industries AB, Financial Statement, 1996)

As part of turnover, products are sold, via distributors, in a further 48 countries worldwide. Production is carried out in 16 factories, divided between 8 countries. 50% of production is carried out in Sweden.

The group ‘s operation is divided into five business areas which are as follows.

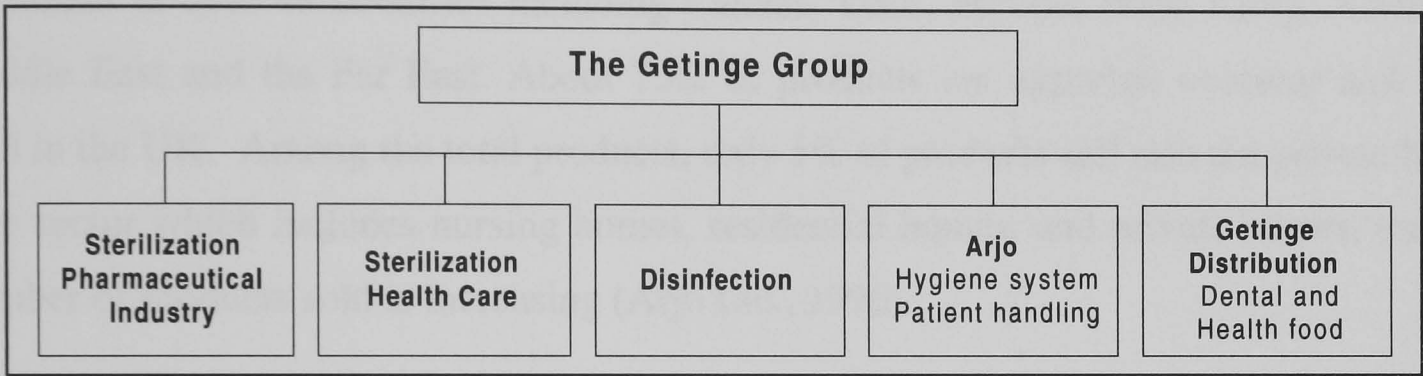


Figure 9-1. The Getinge Group (Source: Getinge Industries AB, Financial Statement, 1996)

The Getinge Group invests approximately 3% of its total turnover in product development. During 1995, resources in the sterilisation business area were concentrated on a European autoclave for the health-care sector and the continued development of system sales for the pharmaceutical industry sector (Getinge Industries AB, Financial Statement, 1996).

The disinfection business area launched a washer for the European market, as well as presenting a fibro-cleaner for the cleaning of flexible endoscopes. In addition, an increased range was introduced for the pharmaceutical industry and laboratories, along with a loading/unloading system. Dental, which is part of Getinge distribution, has continued the development of its private label range. The health food business area has increased its own product concept through acquiring Max Medica (Arjo Ltd., 1997).

Arjo Ltd. has continued the launch of its previously produced hygiene system and complemented its patient care programme. Arjo Ltd. is now undergoing a comprehensive rationalisation programme with the focus on factory specialisation. At Arjo Ltd. in the UK, Gloucester is the centre for patient handling products (Somerton, 1996).

9.3 Arjo Ltd. in the UK

The main interest of Arjo Ltd. in the UK, Gloucester is making patient handling equipment. Somerton (1996) described their main interest as 'lifters of the body. So we actually lift bodies up and move them from a bed to a chair or wheelchair to a bed or into a bath on to a toilet - that is our main job in here'.

The Gloucester division has a big manufacturing plant. 20,000 hoists per year go through hospitals and nursing homes as well as in private homes for moving people around.

Arjo Ltd. products are sold through specially trained representatives and support personnel in over 48 countries including Canada, USA, Europe, Hong Kong, Australia, Middle East and the Far East. About 75% of products are exported overseas and 25% sold in the UK. Among the total products, only 5% of products sell into the private home care sector which includes nursing homes, residential homes, and private homes, but the number of products sold is increasing (Arjo Ltd., 1996).

In the Gloucester division, there are five executive managers of the company. These are the managing director, sales & marketing manager for the group, the manufacturing development manager, production engineering manager and one other manager. They have an equal role to play into the overall management system.

The company structure is divided into sales, services, marketing, production engineering, manufacturing, research & development. Somerton (1996) stated,

We have a very open structure in that everybody talks to each other. I don't like formal lines of communication. There are very informal lines. The marketing people talk directly to the engineering team. We have engineering people, we don't have production engineers or designers, they are all one title. They will talk to the purchasing or the service or the sales or the marketing as and whenever they want.

9.3.1 New product development

In Gloucester, Arjo Ltd. normally introduces three or four new products a year. Somerton (1996), who is in charge of the design department, has been in the company for 3 years since 1994. He was asked to join this company in 1994, because, although Arjo Ltd. is the biggest in the world by a long way in its field, the company had become very stagnant. It had not developed any new products for seven years. In the 3 years since

Somerton joined Arjo Ltd., it has produced 10 new products ranging from relatively small devices through to whole new lifts and lifting concepts.

Somerton (1996) said that the reasons for changing their products are mostly market needs obtained normally from customers' opinions.

9.3.2 Design department

The person in charge of the design department is an executive manager, who is also responsible for the production engineering side of the business.

The design department consists of 32 people among whom industrial designers, technicians, production engineers and design engineers etc. The design department in the truest sense is responsible for the concept of product development all the way through to prototype and getting products actually into production by the manufacturing department and prepared for testing.

Somerton (1996), explained the position of the design team,

In terms of what I call design, this is part of a whole process and this process includes 'How do I make these 2 pieces work together well? If I weld them together, will it break under certain loads?'.... We have a full time industrial designer who works for us and he works very closely with the actual design teams or engineering teams to produce an end result.

9.3.3 Proposal of initial ideas

Anyone can often propose new ideas for change. Somerton (1996) said,

It can be designers, sales people, generally it's our customers who come to us and say, 'We think this product can be improved in the following way'. We will then consider that, to see whether that suggestion is valid and perhaps do something with it or not. It can be anybody from a nurse through to a doctor through to a surgeon. It can also be engineers who work for hospitals who often come back to customer enquiry as well as their own sales people.

9.3.4 Customer opinion feedback

Somerton (1997) claimed,

We have a good relationship with our customers around the world and we are continually getting feedback - more feedback for new products as opposed to lots of feedback on our existing products.

Customer's opinions are obtained through the marketing department and sales department. Somerton (1997) emphasised that customer feedback for new products is gathered through out the whole design process (see Section 9.4) and primary concern is the customer.

9.3.5 Incentive policy

There is no incentive system for in-house people who propose ideas for new product development.

9.3.6 Decision making

When specifications are put forward by the production engineering manager, the specifications will be reviewed by the five senior managers of the company.

There is a relatively informal committee of three senior managers who are the sales & marketing manager for the group, the manufacturing development manager and the production engineering manager.

There are some very formal systems within that informal committee. There is quite a formal prioritisation programme. Somerton (1996) said,

We have at the moment 71 projects that I need to do. We cannot do 71, we haven't got the people. So we have to prioritise to sort that out. We have quite strict rules on how we prioritise our projects. We create computer models of pay back periods against advantages over competition etc.

9.3.7 Design brief

The project team produce a project brief for each project which will include some marketing aspects, costings, proposed numbers of volumes as well as the details, product design information and technical information. It will highlight what risks there are in going into the project and more mundane areas such as which country a product is going to be sold to.

Somerton (1996) said,

They are not good enough, the design briefs. The design brief is as good as you would need. What we are weak at in this company, and what we are weak at as an industry - all of my competitors are as well - is the marketing input. This industry is very much design/product driven, it has been for the last 20 years. It's starting to

get better'. The design brief is part of the larger project brief. A designer can request to have it modified but the request may be refused.

9.3.8 Design strategy

There is no formal design strategy for this company. Somerton (1996) said,

Strategy as such is what we want to do with a product. Is it just going into a hospital and satisfy all needs, or is this one particular product that suits a particular part of that need? We will then consult what I instigated in the last 18 months. I have 3 working groups in the UK, one in Holland, one in America and one in Japan where they are teams of doctors, nurses, a porter who pushes people around and others as well. I go and meet them on a regular basis. I say "This is something we are thinking about doing. We've had a request from wherever, tell me about it. What do you guys think". This is the customer telling me what they think should be included or excluded from this product.

9.4 New product development process

Somerton (1996) said,

We have a design procedure laid down in our ISO 9000 procedures, which we follow. They are very broad outlines only. Each project is different, and is treated differently. There are a whole host of test features that we have to comply with, which are laid down, which we do. We use risk analysis a lot, FMEA we use a lot. The procedure that is settled on is very specific to the project and we just use the ISO 9000 as a very broad outline, as a guidance document.

The design procedures consist of first of all identifying a problem and once the problem is identified the marketing team will produce a specification which is the requirement they think that the customer requires (see Figure 9-2).

The production engineering manager will then take that marketing specification and review it from a technical point of view and produce a specification which is generally a compromise between the technical side and the marketing side.

The specification will be reviewed by the five senior managers who decide whether the project will be carried out or not. The project team will use the specification for the design of the product.

The senior managers will then create a project team. The project team consists of a designer, a production engineer, a buyer and then anybody else they think will be necessary. It will also include all suppliers who they think will be necessary at that time from the very first concepts.

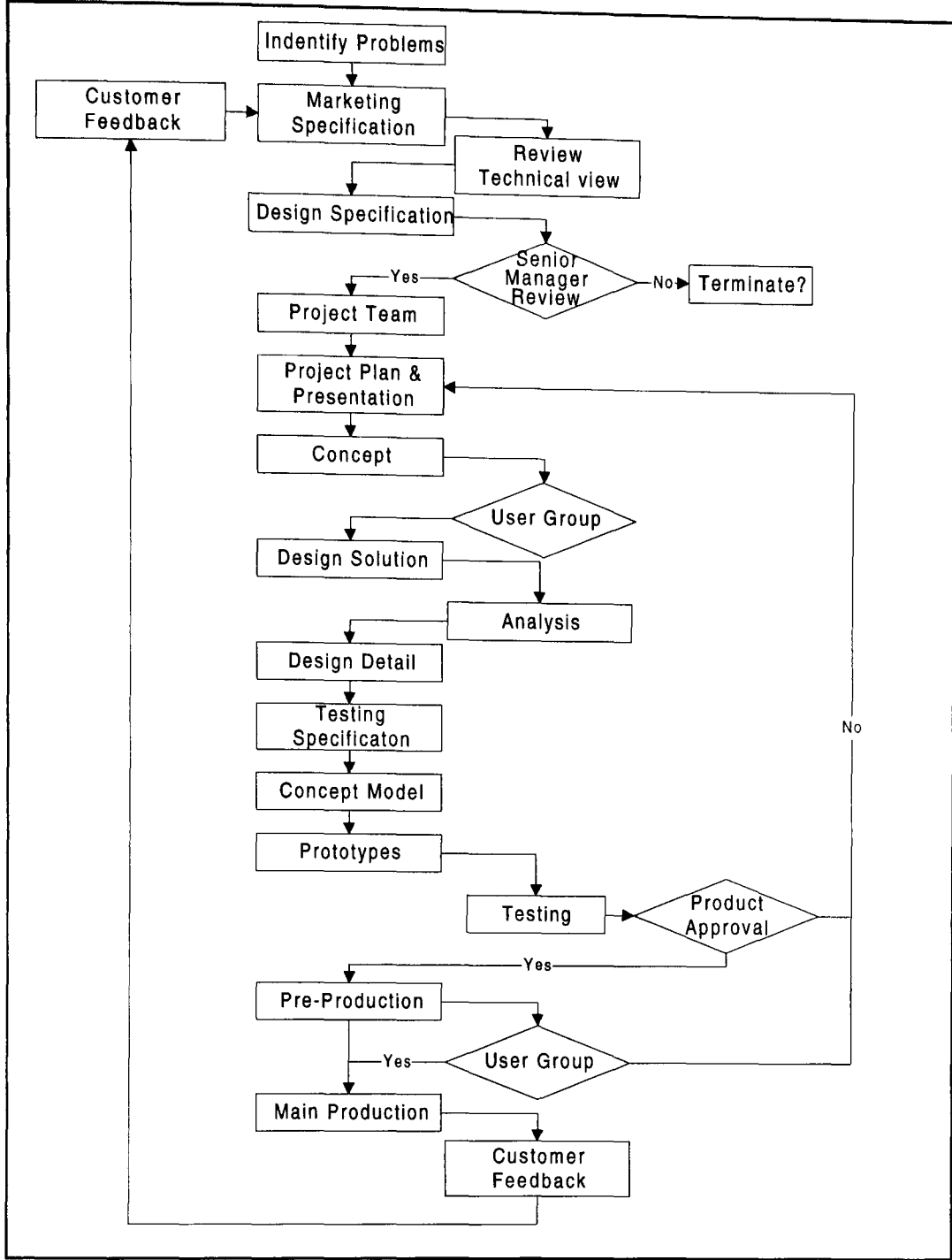


Figure 9-2. Design procedure - design process at Arjo Ltd.
(Constructed by S.Y. Lee-Interview at Arjo Ltd. with Mr. Somerton)

With the project team’s help they will then sit down and produce a project plan. That project plan will consist of time scales, a budget and getting confirmation of the nominated suppliers.

Once the project team has got that plan in place they will then present it to everybody in the company who they think will be even slightly involved in the project. That could be up to 60 people because it will involve accounts, it will include service and everybody who they can think of as suppliers. The project team does an overall presentation so they all know from the onset what the project team is trying to do.

Once the project team has done that, the project then officially starts and the project team will, depending how innovative the product has to be, either look at the development from an existing product or they will start to think about new concepts and new ideas.

The project team will then set up a user group and this user group will normally consist of 4 or 5 people who are considered to be experts in their field. This would involve occupational therapists, ergonomists and physiotherapists.

The project team will discuss the project with a user group and if the project team need to, they will then possibly ask the user group for some design solutions. However, if the project team assume they have got some design solutions, they will have a number of them. The project team will use an industrial designer. He will then be involved at the beginning of the project to try and analyse the shape and style of the product and some of the manufacturing material to suit.

The project team then analyse all of the different proposals; that can be 5 or 6 different proposals with anything up to 50 different design solutions. They will have a meeting as a relatively concise team and analyse down to 2 or 3 different concepts that are going to be pursued.

If they need to the project team will produce models of those concepts rather than just doing it on paper, at which point the project team decide on which they think is the best concept. Once they have done that they then start to do design detailing with some drawings and start to tie the thing down more, looking at materials. The testing specification is then confirmed.

Once that is done, the project team get to a point where they start to build what is called the concept model. This is a model which is not a prototype model. It is, in fact, before the prototype stage. This model proves various functions, whether it is going to fall-over, stand-up, be strong enough, be of the right size.

If that model passes these tests successfully, 2-3 prototypes will then be produced. These get used for significant testing, such as fatigue testing, static testing, electrical testing.

If these tests are successful and everything is agreed by the management of the company, pre production units will then be produced which can be anything up to 50-60 units

Pre-production units will use production tooling. All through the process suppliers have been involved. The production unit must use any components that are going to be used in production, such as injection mouldings, castings, centred components. If the project team think these components are going to be used in production, then these pre-production runs use them.

The whole test procedure is repeated again and then once everything has been completed satisfactorily then the project team will give the pre production unit to the marketing team with a view of confirming the launch date.

The launch dates for the product would have been set back at the beginning, or an ideal target would be set at the beginning, and when the project team get to the concept model stage the launch date will then be firmed up. A number of meetings with the user groups would have taken place during this process to make sure that what is being designed and built actually does fit, and work can be done to solve any problems that might have developed.

When the pre production units have been built, they are used for field evaluation. Those 50 units typically will be sent to a number of different countries and will be used by patients, handlers or nurses, for something like 2 months. If there are any changes that are needed in design then obviously they have to go back through the loop again. If not, then it can be launched by the sister companies.

9.5 Case study: Sara 2000

9.5.1 Introduction to Sara 2000

The Sara 2000 was modified from Sara Power. A previous version was the Sara originated from the Stella (see Figure 9-3).

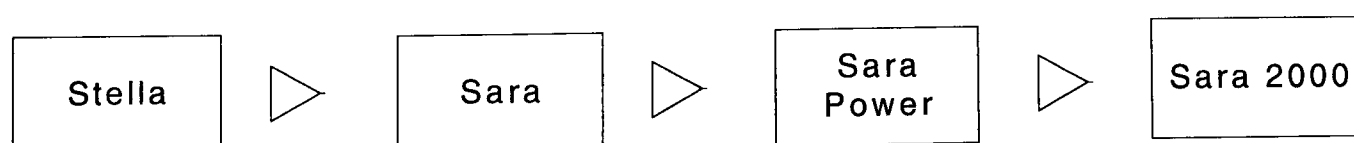


Figure 9-3. Product modifications for Sara 2000

The concept of the standing and raising aid was first introduced by Arjo Mecanuids Ltd in 1987 with the Stella. A standing, toileting, elevating, lifting and lowering aid, the Stella was designed to take the weight off nurses' backs in handling patients for dressing and toileting purposes (Wilson, 1990).

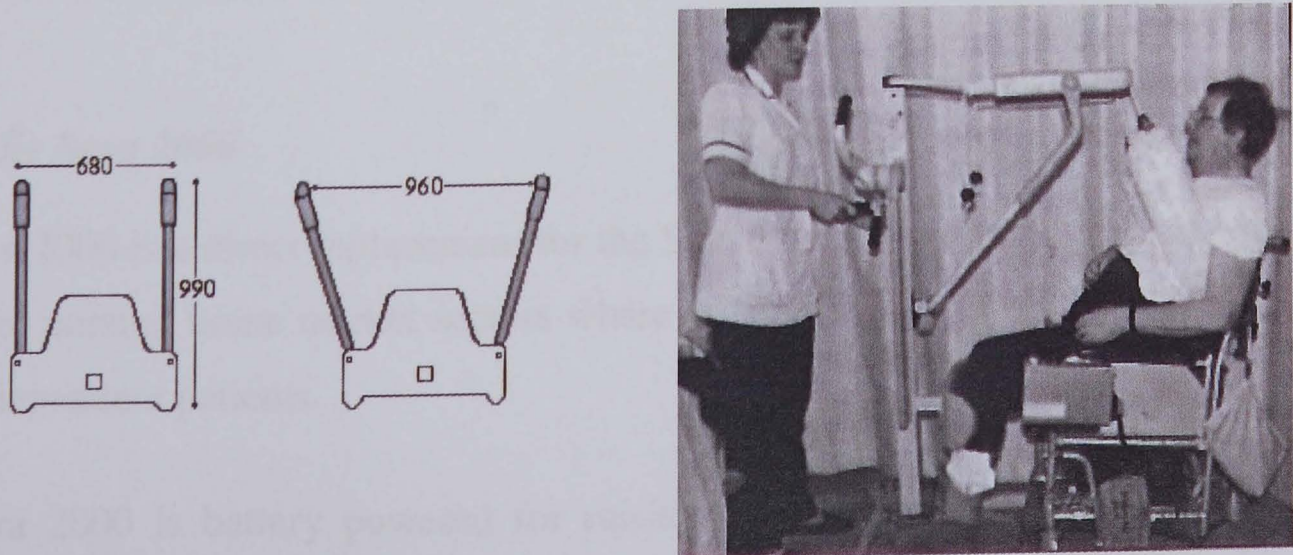
Since the introduction of the Stella, the concept of the standing and raising aid product has taken hold significantly within the healthcare market and is now holding a market value in excess of £10 million. The total number of units distributed world wide each year is estimated by the company to be approximately 10,000 with an average unit price of £1600 in 1995/6 (Standing Raising Aids, 1996).

Throughout the early nineties, market hold and share was dominated by the Sara, Arjo Ltd.'s standing and raising aid (see Figure 9-4). This manual mobile lifter has become generic over the last four years, but is now seen to be somewhat old-fashioned bearing in mind, its size, aesthetic look, and lack of power (Wilson, 1990).

Despite some of the same issues being held against the Sara Power which is the older version of Sara 2000, the introduction of this product has maintained the Arjo Ltd. market share at around about 45% over the last two years and is currently still growing.

However, the entry into the market of many low-priced powered products has now started to erode the market share held by Arjo Ltd., in particular in the care-home and small hospital market sectors where the Sara Power had functioned well (Standing Raising Aids, 1996).

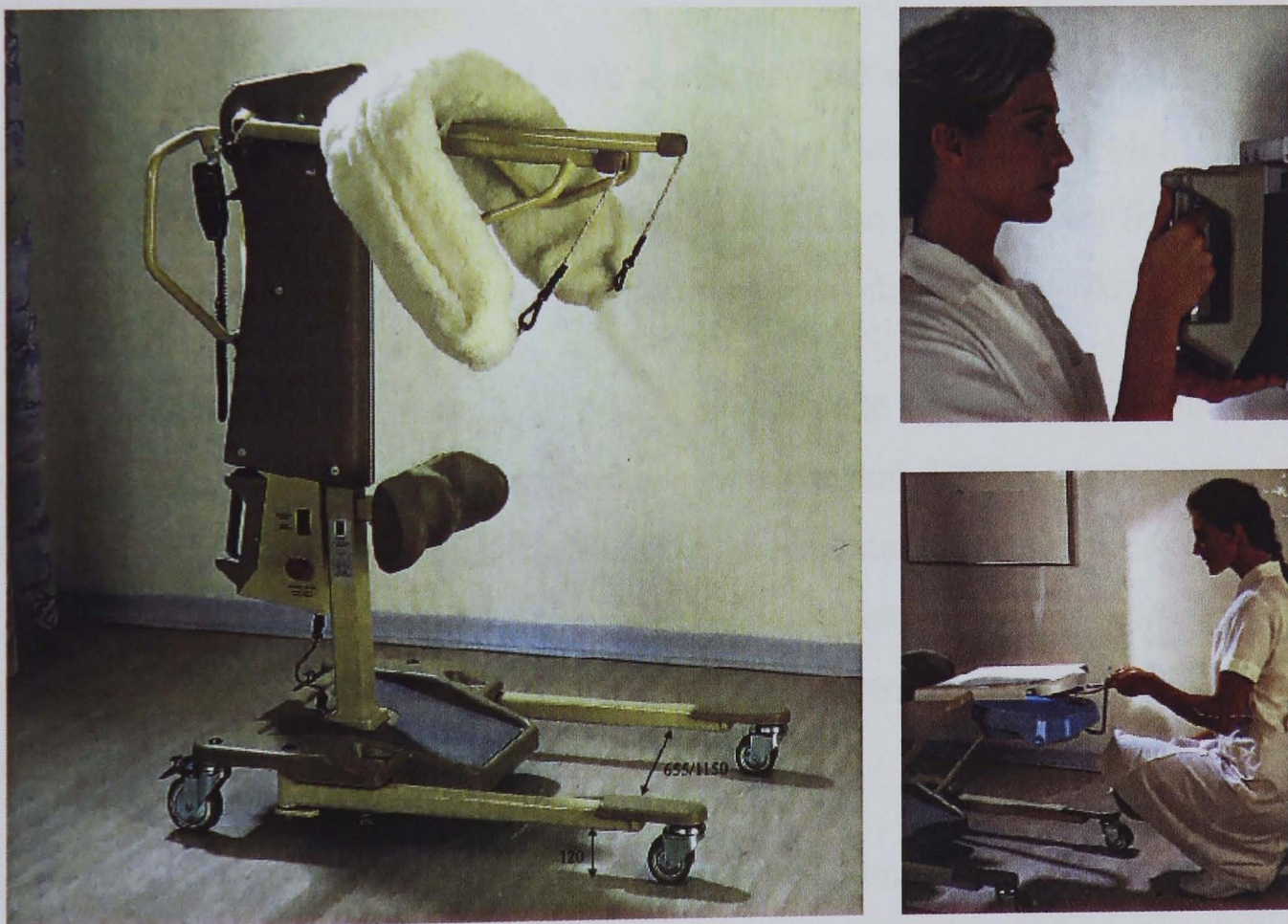
Figure 9-4. Sara (Source: Wilson, Hoists and Lifts, 1990)



There are approximately 5,000 units within the institutional market. The Sara Power shares 55% of them (2750 units) and it has a very strong foothold (Standing Raising Aids, 1996).

Arjo Ltd. realised that two strategies needed to be put in place by Arjo Ltd., firstly to maintain market share in the institutional level, secondly to win and grow market share in the care-home market. The pacemaker to these two strategies were two new products, both similar in design and concept to the Sara 2000 but differing in specification and duty (Standing Raising Aids, 1996).

Figure 9-5. Sara Power (Source: Sara Power leaflet, 1995)



9.5.2 The Sara 2000

The Sara 2000 is a direct replacement for the Sara Power, and is aimed at the institutional and large nursing home market sectors where care is given on a high frequency basis to highly dependent patients.

The Sara 2000 is battery powered for raising/lowering as well as opening/closing of chassis legs. Both functions are controlled via the hand control with two 24V removable

and rechargeable batteries, and a charging unit. It also includes a 5V watertight handset, low friction castors, two rear castors with brakes, powered opening and closing of chassis legs. There is a safety stop if the lifting yoke runs into an obstacle when lowering. The lifting/lowering action stops immediately when the push button is released. The rated load capacity is to lift 28 stone (400 lb., 180 kg) driven by a powered battery that offers up to 100 lifts per battery charge (Sara 2000 Catalogue, 1995).

The Sara 2000 is compact and benefits from the introduction of new castors that are claimed to be the best and with easiest manoeuvrability of any hoist on the market place. With aesthetic design and good looks, the Sara 2000 also incorporates side handlebars giving a comfortable and user-friendly ergonomic approach to manual handling when standing and raising patients.

A new concept of lifting is offered with the Sara 2000 with the incorporation of a new transfer sling. This enables the nurse to lift patients from either a wheelchair or maybe a bedside and transport them in a sitting position, with the patient's feet firmly on the foot rest containing a high level of security and dignity (Standing Raising Aids, 1996).

Crucially, the Sara 2000 was been priced to compete aggressively with competitive products in a high-quality, high-performance environment. With a market price of below £3000, the overall objective of Sara 2000 is to 'occupy' market share within the institutional sector. This will be done with increased activity of the sales force together with focused advertising and promotional activities through direct mail and marketing (Standing Raising Aids, 1996).

Alongside the Arjo Ltd. Maxilift, the Sara 2000 is claimed to be the ideal and essential standing and raising aid incorporating transfer opportunities for all large dependent units.

It was initiated by our customers. The original product was designed in a very classic English way. This story is quite involved but we have now had an opportunity where we redesigned, we've introduced some styling into it. We've reduced cost and we have a better product. Sara 2000 it's called - Standing And Raising Aid. That's what it does (Somerton, 1996).

Figure 9-6. Product data for Sara 2000
(Source: Sara 2000 leaflet, 1995)

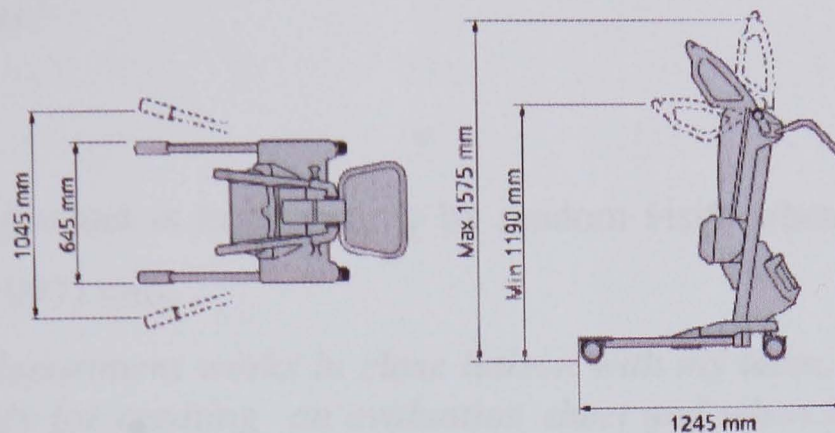
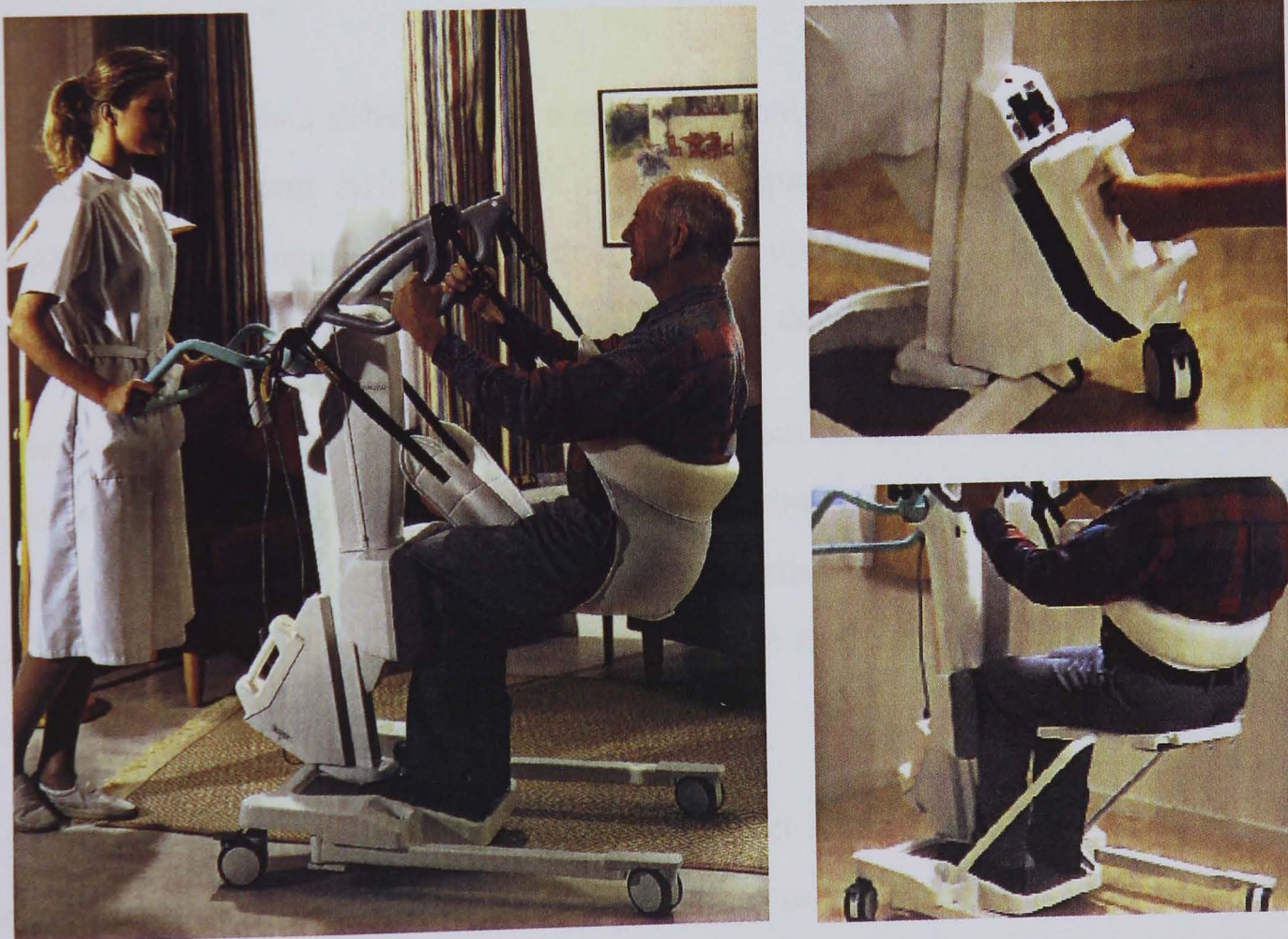


Figure 9-7. Sara 2000
(Source: Sara 2000 leaflet, 1995)



9.5.3 Reasons for modifications

The reasons for modification of the Sara 2000, Somerton (1996) explained, were to improve product performance, reduce costs significantly and to improve the styling of the product, to make it more user friendly in the hospital. These were the 3 main drivers but the biggest driver was undoubtedly cost.

This factor had been proposed by customers. Somerton (1996) said,

They were upset about the price of the product, so they were saying to us 'Can you please reduce the product costs, or sales price or price of the product?' Equally, the more professional buyer saying 'Is there any way of improving the lift that the product produces?'

9.5.4 Evaluation

Evaluation of the product is made mainly by random visits where the product is being used. Somerton (1997) said,

the marketing department works in close liaison with my team. We actually share the responsibility for creating an evaluation sheet and when the product goes on field trials there is an evaluation sheet that goes with them, and we will randomly go and visit one or two. Just to see how they are getting on. They generally don't know we are coming, and we just see how they are getting on with the product.

9.6 Summary

Arjo Ltd. Gloucester is a subsidiary of a multi-national firm, the Getinge Group. In terms of product development Arjo Ltd. UK operates separately. The design department is responsible for the concept of product development up to the prototype stage after which production is the responsibility of the manufacturing department.

New product development ideas generally come from customer feedback and this is the main source for idea generating. These ideas are proposed by the marketing department on a specification form. Once the design specification has been viewed from both the marketing and technical point of views, decisions are made by a formal committee of five senior managers.

The company runs on a project basis and the project teams control each project through the product development process. The project team produce a design brief. The fact that the design brief is part of the larger project brief is recognised as a weak point in the company need.

Design plays a very important role in both the initiation and decision making of project formulation. The product engineering manager dominates the whole process with strong help from marketing. New product development is driven by three main aims by an increase in product performance, improvement of the styling of the product and reduction

of costs. Among them the biggest driver is reducing costs. The process of project formulation is similar even in different types of modification. The case study of Sara 2000 is a typical example.

The majority of the customer's opinions come through the marketing department or sales department. Although Somerton claims that users' opinions do have an important place in design procedures it seems that regulatory matters have a greater impact on design procedures.

New products are developed by a strong engineering department. In the engineering department, each new product is developed by a project team which consists of various people from different departments. An industrial designer works with a project team or engineering teams to produce an end result. At the beginning of each project, an industrial designer is involved with analysing the shape and style of the product and some of the manufacturing material, etc.

The projects for product development or modification come from a variety of sources. Although Somerton claims that customers can propose product change, and the marketing team produce a specification which is the requirements they think that the customer requires, this idealised situation does not happen often. In practice, the people who propose projects for product development are those who are expected to do so. They may be a marketing or sales team, engineering department, design department, research & development department and a combination of different departments / people etc.

The main reason for the development of the Sara 2000 was that the existing one was old-fashioned bearing in mind, its size, aesthetic look, and lack of power to appeal to the customer. The 3 main drivers to improve product performance were to reduce costs significantly, improve the styling of the product and make it more user friendly in the hospital. But the biggest driver was cost.

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Chapter 10

Gambro

CHAPTER 10. GAMBRO

10.1 Introduction

This case study provides examples of product development in a multinational firm, the Gambro group. Section 2 starts with an overview of the Gambro group operation, their market and products. Section 3 discusses Gambro UK and their activities in relationship with headquarters in Sweden. Section 4 illustrates the general product development process at Lund in Sweden. It covers the design department, new product development, the proposal of initial ideas, incentive policy, customer opinion input, decision making and the design brief. Section 5 looks at the designing of the AK 100 dialysis equipment, its development and reasons for modification. The final section summarises the pattern of the new product development process at Gambro.

10.2 Gambro group

Gambro is a Swedish firm that occupies a leading position in the dialysis products and markets areas. Gambro is a global company operating in medical technology with 98 % of group sales outside of Sweden. The group's operations are co-ordinated through the parent company, Gambro AB, in Lund, southern Sweden.

The group is active in two business segments, renal care and medical technology products. Renal care, which accounts for about 80% of sales, consists of two business areas, dialysis products and dialysis care. The other segment, medical technology products, consists of two business areas: cardiopulmonary care, and blood component technology. These business areas, with manufacturing operations, have resources and responsibility for conducting their own research and development activities (Gambro Annual Report, 1996).

Marketing and sales are mainly carried out through Gambro's own sales companies. With total sales of 10,964 SEKm in Swedish currency (about £ 997m, see Table 10-1) the group has more than 90 subsidiaries in 26 countries, with representation in a large number of other countries and 26 production units in 13 countries (Gambro Annual Report, 1996).

Table 10-1. Trend of sales by business area (Source: Gambro Annual Report, 1996)

SEK in millions	1 Jan-31 Dec, 1996	1 Jan-31 Dec, 1995
Dialysis Products	6,798 (+6%) *	6,884
Dialysis Care	2,417 (+78%) *	1,449
Internal sales within business segment	- 200	- 121
Renal Care	9,015 (+18%) *	8,212
Cardiopulmonary Care	1,064 (+4%) **	1,130
Blood Component Technology	885 (+16%) *	815
Other Medical Equipment	1,949 (+9%) **	1,945
Sales	10,964 (+15%) **	10,157

* The figures in parentheses relate to increases after adjustment for exchange-rate effects.

** The figures in parentheses relate to increases after adjustment of exchange-rate effects and the divestment of Patient Monitoring

In 1997, the group had approximately 17,000 employees. Research and development units are located in Sweden, Germany, Japan and the United States (Technology in the Service of Human Life, 1997).

The Gambro group consists of three worldwide companies, viz., Gambro, Hospal and Cobe. Gambro was founded in 1964. The company's business objective was to develop, produce and market 'the artificial kidney', which had been invented as early as 1943 by Professor Nils Alwall. Three years later, the world's first disposable artificial kidney went into production and Gambro started to manufacture its first dialysis machine. In 1973, Gambro introduced a plate dialyser completely made of plastic, and in 1977 the company launched the world's first computer controlled dialysis machine, the AK-10. Hospal was established in 1969, as the French dialysis company, which is headquartered in Basel in Switzerland and has plants in Lyon, France, and Mirandola, Italy. Hospal was acquired by Gambro in 1987.

Cobe, the U.S. company, based in Denver, Colorado was formed in 1964. Several products, such as membrane oxygenators for use in cardiovascular surgery, blood separators, auto-transfusion equipment and dialysis machines have been developed for the world market by Cobe researchers. In June 1990, Gambro acquired Cobe Laboratories (Gambro AB, 1996).

Felding (1997), the international product manager, further explained that all three parts of the group manufacture dialysis machines, but each group has a different profile, in that Gambro offer different machines for differing market forces. For instance, in America, the Gambro group sells Cobe machines because it is believed that the Cobe company is

more adapted to American needs and ideas. Hospal mainly sells machines in France, Spain and Italy, although Gambro machines also sell in France. In fact, Gambro's machines are sold all over the world, except in the USA.

10.2.1 Market

The market for dialysis products, which is valued at approximately SEK 40 billion (£ 13.7 billion), is growing at a rate of about 10 percent per year. It is a global market, covering a substantial part of the industrialised world. It is also growing rapidly in the Asia Pacific region and Latin America as economic conditions in these parts of the world improve. On the whole, there is a substantial potential for dialysis business in developing countries (Gambro Annual Report, 1996).

The leading companies in the global market for dialysis products are Gambro in Sweden, Baxter in the U.S. and Fresenius in Germany. In 1996, as estimated by Gambro, the company led the haemo dialysis market with 21% of market sales and they had 16% of the total market sales. This can be seen in the following table.

Table 10-2. The shares of global market
(Source: Gambro Annual Report, 1996)

	Gambro	Baxter	Fresenius
Haemo dialysis	21%	6%	16%
Peritoneal dialysis	2%	70%	16%
Totals	16%	21%	16%

10.2.2 Products

The most important products used in haemo dialysis are dialysers, dialysis machines, dialysis concentrate and bloodlines.

The Gambro group manufactures dialysis machines of varying degrees of complexity and in different price categories. Historically, many products have been developed since 1949 when they started to develop drum types of dialyser (see Table 10-3). In the 1990's Gambro started to produce their own brand dialysis machines, namely, the AK 90, AK 95, AK 100, AK 200, AK 100 ULTRA and AK 200 ULTRA.

Table 10-3. History of product development (Source: Gambro AB, 1996)

Year	Product & Type	Etc.
1949	Drum	
1965	Filter for haemo dialysis ; Alwall's model	
1967	AK-1 (dialysis machine)	Wall mounted
1971	AK-3	Fully automatic
1974-1975	AK-5	Acetate dialysis
1977	AK-10 (micro computer)	BiCarbonate
1980	AK-10	HFM system
1981-1982	WRO	
1985	GHS-10	
1987	BiCart	
1988	AK 90	
1990's	AK 100, AK 200, AK 95, AK 100 ULTRA, AK 200 ULTRA	

The dialysis machines are manufactured under three brand names - Gambro, Cobe and Hospal - in Sweden, the U.S. and Italy, respectively.

The dialyser contain membranes that have varying characteristics. They may be cellulose or sophisticated synthetic membranes, more or less biocompatible, and offer a high or low degree of permeability. The group produces four different synthetic membranes that meet varying requirements. The membranes are enclosed in plastic dialyser manufactured in one of Gambro's six dialyser plants.

The bloodlines, which conduct the blood to the dialyser and then back to the body, are manufactured in plants in Europe, the U.S. and Asia. The dialysis fluid is produced from dialysis concentrate that is made in Germany and Italy. The bicarbonate content in the fluid is supplied by Gambro's BiCart bicarbonate cartridge that is manufactured in the Swedish plant (Gambro AB, 1996).

From the very start, sales of disposable products - dialysers, bloodlines, bicarbonate cartridges and dialysis concentrate - have accounted for the greater part of revenues since all patients have to use such products three times a week. With the pressure on prices of disposable products in recent years, dialysis machines have become an increasingly important source of revenue (Gambro Annual Report, 1996).

Overall of worldwide market share of all companies, the European total is 58%, of this, 35% is shared by Gambro, 13% by Hospal and 10% by Cobe. A worldwide share is 20-22% (see Table 10-4).

Table 10-4. Gambro's share of global market
Source: Gambro Annual Report, 1996)

Product	Gambro's share of global market
Dialysers	> 20%
Dialysis machines, service	> 20%
Bloodlines	> 25%
Concentrate, bicarbonate cartridges	> 10%

Anderson (1997), the Marketing Manager, points out that markets are getting competitive, and the reasons are economics and technology based. But the product life cycle is different to each country. Felding (1997) claimed, *'We want them to buy our machine again. It's like the car industry; if you've had a certain car for 7 years from new, then you'd like to have new model'*. He explained that in some countries, hospitals might have severe financial problems, and also will probably try to extend the life of the machine. The problem is that if they try to keep the older machine it needs more repairs, just like a car. For the first 7-8 years there is a check up every year. Hospitals simply pay for the filter and other parts, but after this time, motors start to get worn, and more complete units have to be replaced. He said, *'That is why 7-12 years is expected. I see that some clinics have exchanged their AK 100 to an AK 200 now'*. But in the UK, older machines, for example the AK-10, have been in use in hospitals for over 17 years. This shows that the product life cycle is different in each country and is affected by the healthcare system and hospital budgets, etc.

10.3 Gambro London, UK

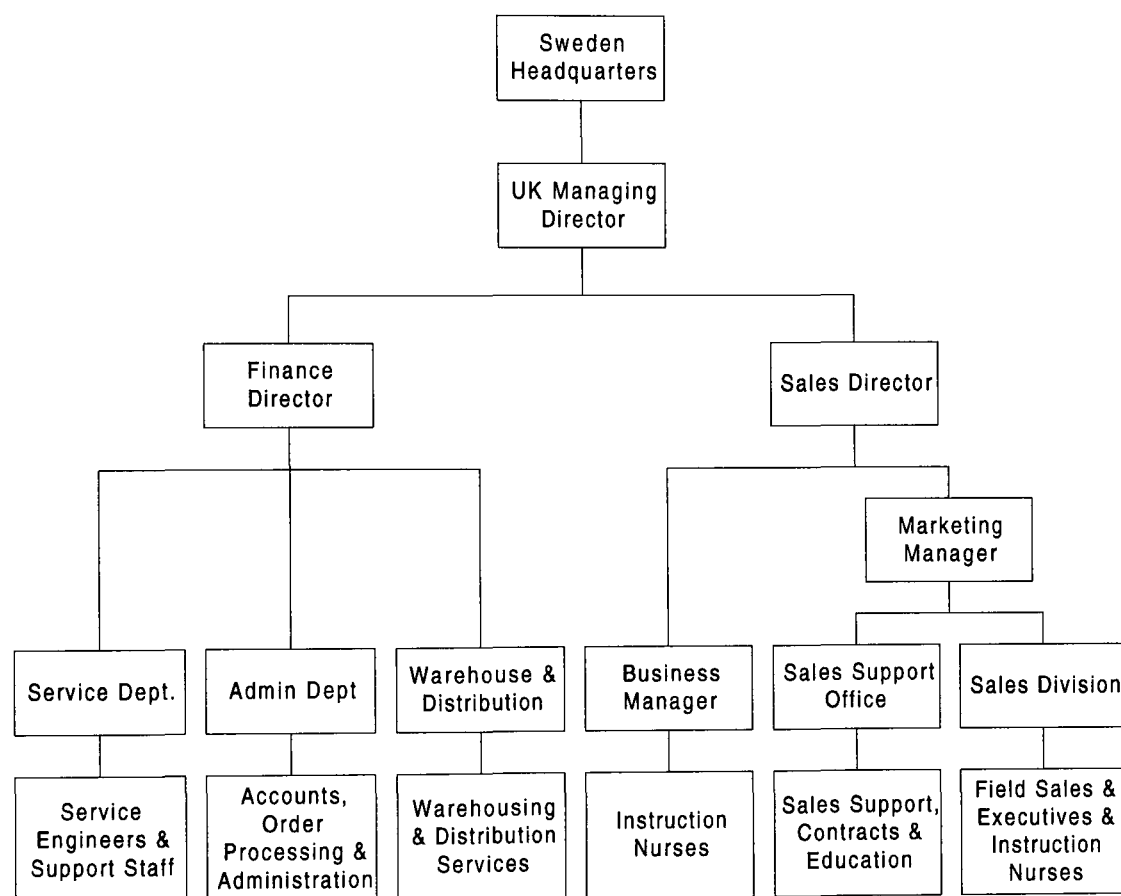
Gambro London is a subsidiary of the Gambro group in Sweden. Gambro London sells dialysis machines, disposable bloodlines and dialysis filters and a whole range of different products in relation to diffusion therapies, etc.

Gambro UK concentrate on the intensive care market under the chronic haemo dialysis market. The company is also involved with APD (Automated Peritoneal Dialysis) and CAPD (Continuous Ambulatory Peritoneal Dialysis) that they operate within niche areas (Anderson, 1997).

A total of 60 people were employed by Gambro UK in 1997. The person in charge of Gambro London is the Managing Director who comes from the headquarters in Sweden.

He runs the operations of product sales for the UK market and he also acts as sales director. He is not only responsible to the UK Managing Director for the profit figures which have to be delivered from the UK to Swedish head office several times each year but also to the central marketing organisation in Sweden when investment for new product development is required (see Figure 10-1). Customer feedback is directly reported to headquarters by the managing director and the information is exchanged (Anderson, 1997).

Figure 10-1. Gambro London - organisational structure



Anderson (1997), the Marketing Manager, stated that the home dialysis market in the UK is very pre-eminent, and Gambro in Germany and Holland have very strong demand for home dialysis equipment. He pointed out that there are problems with the equipment which is under supply in the UK. For example, 12,000 dialysis machines are used in the home environment and half of them are haemo dialysis and the rest are peritoneal dialysis, but in France they have the same population but home dialysis users are 22,000 people. The reasons given by him are that in the UK, until 6-7 years ago, people who were under 15 or older than 55 people who were not married could not get dialysis machines because the machines generally needed to be operated with somebody's help. The other reason is that the transplant rate in the UK is very low compared with other European countries. During the 6-7 years time there had been only 1700-1800 donors in the UK.

10.4 New product development

New products are developed by Gambro, Lund in Sweden. When the company develop new products they all start with a project group which has a project leader, administrator and various types of design engineers. Felding (1997) stated that as an international product manager, he is also involved in the project when he receives a written specification in order to make sure that the specification is covered.

The new product is tested in a design quality department. The design quality department exists to make sure that the product is safe from a mechanical point of view. Any faults with size or sharp edges are also checked. Tests are carried out to see if it is possible to manufacture the product, and the software is also tested to check that the product responds in the correct way (Felding, 1997).

10.4.1 Design department

The engineering department is responsible for the design and development of a new products and consists of electrical engineers, software engineers and mechanical engineers. Felding explained that the company mainly works with engineers. Sometimes when a new product is being tested they discuss design matters with the industrial designer. He further said there are many cases where the design is blocked due to physical limitations, so they need to deal with the design engineers.

There are 3 parts to the development, which are a) Mechanical - boxes, pumps so on, b) Electronics - PC boards, electro circuits and c) Software. All of these components go hand in hand. Felding stated that the development time and cost to make a mechanical part is not a big job, similarly with the electronic boards. The time consuming part is software because it is an operator interface. Although it is quite easy to set the temperature to 37°C, there needs to be an alarm so that the temperature is strictly controlled, with alarms that go off when limits are reached.

10.4.2 Involvement of the industrial designer

There is no industrial designer hired specifically by Gambro but previously the company had involved industrial designers a few times. Felding gave two examples where they had involved industrial designers for new product development, for both the AK 100 and

the AK 200 dialysis machine.

When the company started to make the AK 100 dialysis machine there was a big challenge to the Gambro engineers to develop new hardware and software. Normally, the company produces the machines from the engineering design point of view. The AK 100 project was such a big change for the company that they hired industrial designers. Felding stated that the industrial designers wanted to do so much which was impossible. In the end the company had to settle for more realistic engineering design.

The AK 200 was more limited because Gambro wanted to keep it like the AK 100, in which the overall machine concept remains basically unchanged, but the company wanted some changes in design and operator interface. Although the AK 200 looks very similar to the AK 100, it has many new simpler developments, such as a larger display to present treatment data graphically as well as digitally; also, the height of the stand and the viewing angle of the panel are adjustable for ergonomics, etc.

Felding, the international product manager, hired an industrial designer whose main aim was to simplify the idea, in design areas such as the cartridges, the surrounds, the soft pack, the stands, the lines and the many of the accessories. In fact, Gambro wanted to make a new machine but wanted to maintain a lot of the good aspects of the AK 100 because the concept of that machine was so popular, they did not want to discard the original model.

Felding stated that it was something that the design engineer had begun to look at before she started working or any modifications. The company wanted to keep their original concept. She started to analyse different ideas about a part of the appearance, for example, sharp corners, panel layout and colours. She proposed six different colours, and some modifications to the panel layout.

Felding said they needed to use the same blood lines as in the AK 100 machine, otherwise hospitals would have rejected a new machine. Therefore they needed to have a double set of blood lines. Blood lines take up a lot of space in storage rooms so pumps have to be mounted in certain ways.

The design engineer was very restricted in what she was allowed to do. The company wanted something that could be up and running quickly, while still maintaining the familiar look of the AK 100. She suggested making the bigger machine look smaller, and proposed a grey and blue colour to make the front components look softer. With all these changes, the machine was presented to the advisory board and it was finally accepted.

Felding further said,

It represents a new machine. But the company has to keep the handling simple. We found when we introduced the new machine to those who had the AK 100 before, we had special instructors going out, and we were educating the nurses in half an hour. The nurses said there was no problem with using this machine because it's so logical. We use this kind of logic and that is very important nowadays. It's easy and fast to learn.

Anderson (1997) also claimed that the company takes a standard machine and then modifies it without cost implication. They take advantage of an existing product through the modification rather than redesigning a whole product.

10.4.3 Proposal of initial ideas

The advisory meeting presents all initial ideas. Initial ideas come from a variety of origins and are presented at advisory meetings by representatives of the managers from each country's Gambro subsidiaries.

Sometimes a new invention comes from a research or development department but in most cases the marketing team come up with new ideas.

Initial ideas can also come from customer feedback. The company also gathers ideas from different branches of Gambro.

Any of these ideas from whatever source are presented at advisory board meetings. From these meetings Gambro is able to obtain different ideas from different market places. Felding gave examples; the company can find out what is happening in the UK or in Germany, which treatment is becoming popular, what needs to be done faster or easier.

Therefore the advisory board meetings are treated as a very important forum in which ideas are collected and discussions can be held. Sometimes, if something is happening in one market, but not in the others, modifications can be made to a machine so that it can

adapt to various countries' requirements.

An example is the disinfection of the dialysis machines after treatment. Staff must disinfect a machine before they can connect the next patient. In Scandinavia, a heated disinfection is done more or less between every treatment. Many people do not want to handle chemicals, because chemical disinfection is rather strong and smelly. In southern Europe, France, Italy or Spain, chlorine bleach is used for disinfection, which creates a strong smell when people come to hospital. In Germany, concentrates are used that give a lot of precipitation in the machine. This calcium carbonate precipitation means that they have to run an acetic acid clean very often. Therefore, Gambro need to cater for different national requirements for different countries. It is important to listen because everyone has different ideas.

According to Felding (1997), Gambro receive a lot of customer input when they present the machines at international exhibitions. At Gambro's European annual meeting, customers approach Gambro and suggest changes to machines. One of Felding's jobs is to collect good ideas and then discuss them at the advisory board.

If these ideas are approved he asks the development department to implement the next stage, for example, the software. That department can make software and mechanical change.

10.4.4 Customer opinion feedback

Customer opinions are gathered through the sales people by talking to hospital staff, although ethically and commercially they can not talk directly to patients. A consultant decides the treatment, whether haemo or peritoneal treatment is required. The company also has close contact with the kidney patient associations of different countries, such as the British Kidney Patient Association, and then the company obtains feedback from them. This information is then sent to Sweden for further development (Anderson, 1997).

Anderson stated that medical equipment is different from consumer products. It concerns human life and without that treatment they will die. Therefore the patients have no choice. It is not a simple decision of saying, 'I will buy a TV set tomorrow'. He believes

that the consumer's opinion has to fit into those machines but in a convenient way because one reason is that the user group is getting old.

Felding stated there are a number of 'customers' for their machines. One is the doctor who prescribes the treatment. Another is the nurse who wants a machine which is easy to use and reliable. The technician is another customer, because he has to repair the machine. The administrator or accounts department is another customer because they make the decision of which product to buy. One very important customer is the patient who wants machines which are silent, reliable, give no alarms and offer efficient treatment as quickly as possible. Felding believes that Gambro must make sure that all of these 'customers' are happy in order to sell their machines.

10.4.5. Incentive policy

There is no incentive policy for in-house people who propose ideas for new product development.

10.4.6 Decision making

The product management meeting presents their ideas and discusses them and then presents ideas to the managing board of the company. Felding stated that cost determines the next step. If it is a small project he can decide to do that project himself. If more money, people, and hours are needed, then the company has to sign a project contract. Therefore, most decisions are made at the advisory board meetings. These meetings are held 4 times a year.

10.4.7 Design brief

When the company have a new option, they produce a specification and then they hold an advisory board meeting at which ideas are shared. One representative from each market is normally present. The company collects ideas from the 7 biggest markets which are the UK, Germany, France, Italy, Holland, Belgium and Scandinavia. Ideas are discussed and then forwarded to the president in order to gain approval to start a big project. The design brief is a part of the specification and is presented by the marketing department to the advisory board meeting (Felding, 1997).

10.4.8 Design strategy

There is no design strategy for the company but sometimes a marketing strategy is presented for each project scheduled for new product development. Felding believes that the Gambro name has a high standing in the medical products world. He believes that simplicity, ease of learning and reliability of their products are the most important factors in their 'customers' perception of the company. He further said,

Gambro is known for the BiCart which made life easier for the nurse, as well as for its education follow up and service support, the fact that Gambro representatives 'speak to the customer'.

10.5 New product development process

Anderson (1997) claims that an idea is developed and researched as an in-house concept and it focuses on a couple of markets and is identified by a couple of pilot centres. The company organises the ethical community and monitoring through to Sweden, theoretically and practically. And then they produce paper work to the regulatory authorities for the standardisation product.

New product development starts with generating ideas from a market survey through to the marketing people. Felding writes design specifications but he always discuss these with the advisory board to make sure that an idea will be suitable for everyone. He said,

Otherwise, if I speak to only one customer it might be a good idea for him but it will not be suitable for another person. That is sometimes treated as a problem, in that we need to make something that is both very universal and flexible. That is the challenge.

He forwards the ideas to the relevant department, where they are turned into technical specifications. He writes the marketing or customer specifications and then the company have meetings and reviews and if accepted, the idea is then implemented.

Even after the company has released a new machine, there will be continuous development for the following year since new software changes all the time. He further said,

You can not develop a product and say that it is fine, nothing more needs to be done.

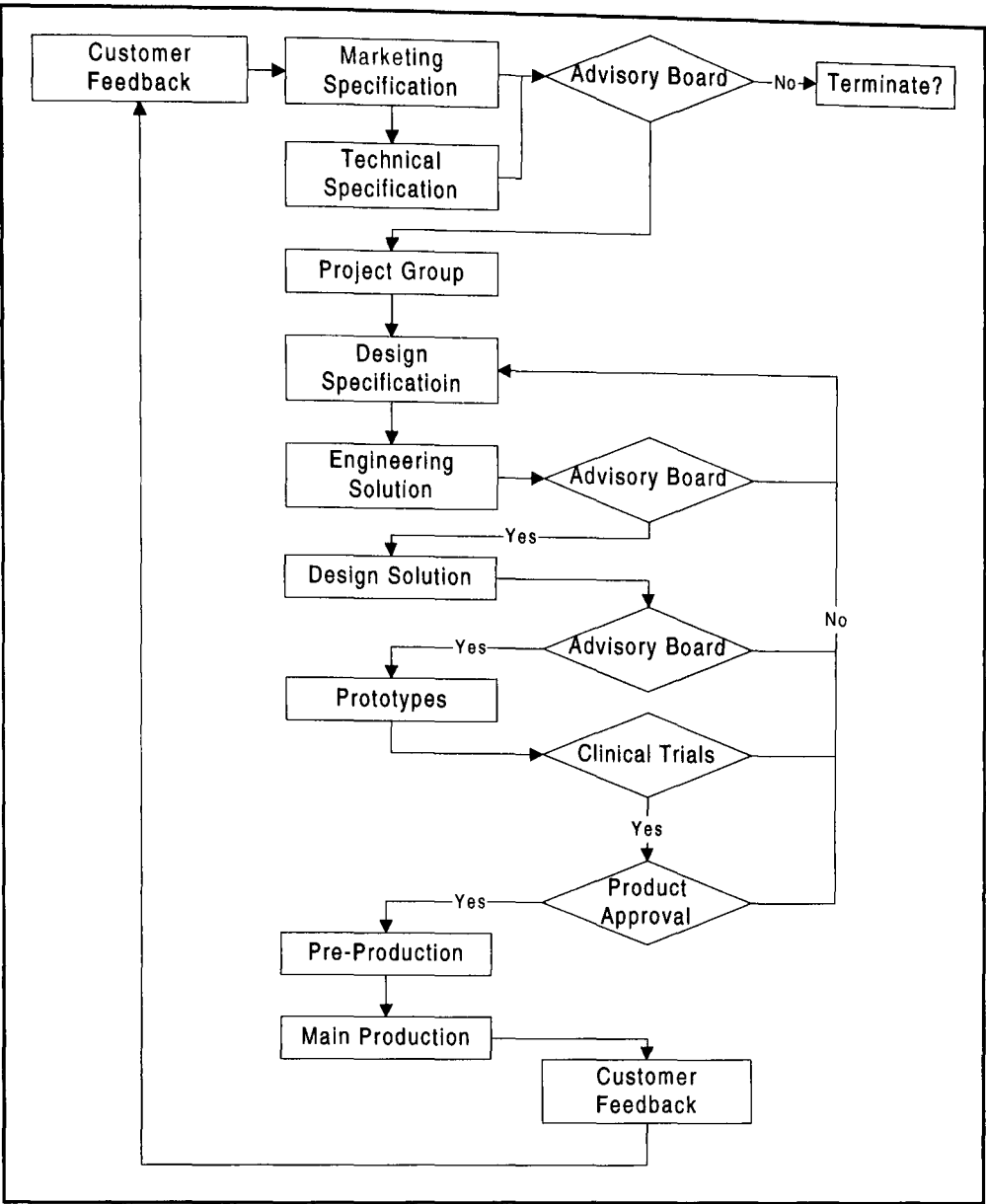


Figure 10-2. Design procedure - design process at Gambro
(Constructed by S.Y. Lee-Interview at Gambro with Mr. Felding)

10.6 Case study: AK 100 haemo dialysis

10.6.1 Introduction to haemo dialysis

To survive, patients with end-stage renal failure require kidney transplantation or dialysis. Haemo dialysis (HD) is, in most parts of the world, the most common form of dialysis for patients with chronic renal failure. In haemo dialysis, blood is taken out of the body and passed through an artificial kidney - the dialyser - where it is purified. Inside the dialyser the blood comes in contact with a special dialysis fluid. The blood and the fluid are kept separated by a thin semi-permeable membrane through which excess fluid and uremic toxins may pass (Gambro Research, 1996).

The entire process is carefully controlled and monitored by a dialysis machine. For most patients the dialysis procedure takes 4-5 hours (in the USA, 3hours), and has to be repeated three times a week. Other forms of haemo dialysis are haemo diafiltration (HDF) and haemo filtration (HF).

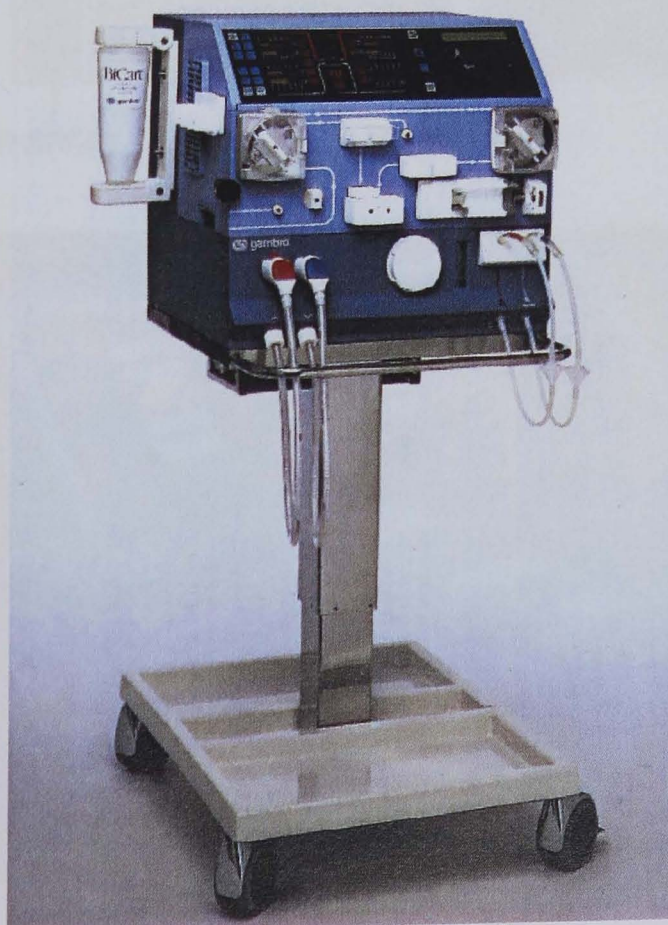
Some patients on HD, the elderly and those with co-morbidities, may need to be dialysed in a hospital but those who want can get equally good treatment outside the hospital, in a satellite unit or at home. Since haemo dialysis for many patients is a life-long treatment it is important to adapt it as far as possible to the patient's life style. For society it is desirable to keep the dialysis patients out of the costly hospital environment for as long as possible (Gambro Annual Report, 1996).

10.6.2 AK 100

The dialysing equipment AK 100 was the first machine to fully implement state technology and to fulfil the exacting safety requirements of the European Community Directive concerning medical devices (Anderson, 1997).

All the special software required to run the AK 100 was developed by Gambro engineers. Several types of control panel for the dialysis machine were designed by Gambro. Gambro developed a machine with a TV screen which can communicate to the user. The drawback with this new design was that patients/users might become confused when they have to push through screens with a manual system.

Figure 10-3. AK 100 dialysis machine (Source: AK 100 leaflet, 1996)



There was a different approach with a TV screen machine and this concept has been very well accepted. But users needed to be trained before they could run it directly. Gambro made a machine with a TV screen but it was ‘a catastrophe’ when it came to handling it. So the company had to scrap the project and start all over again.

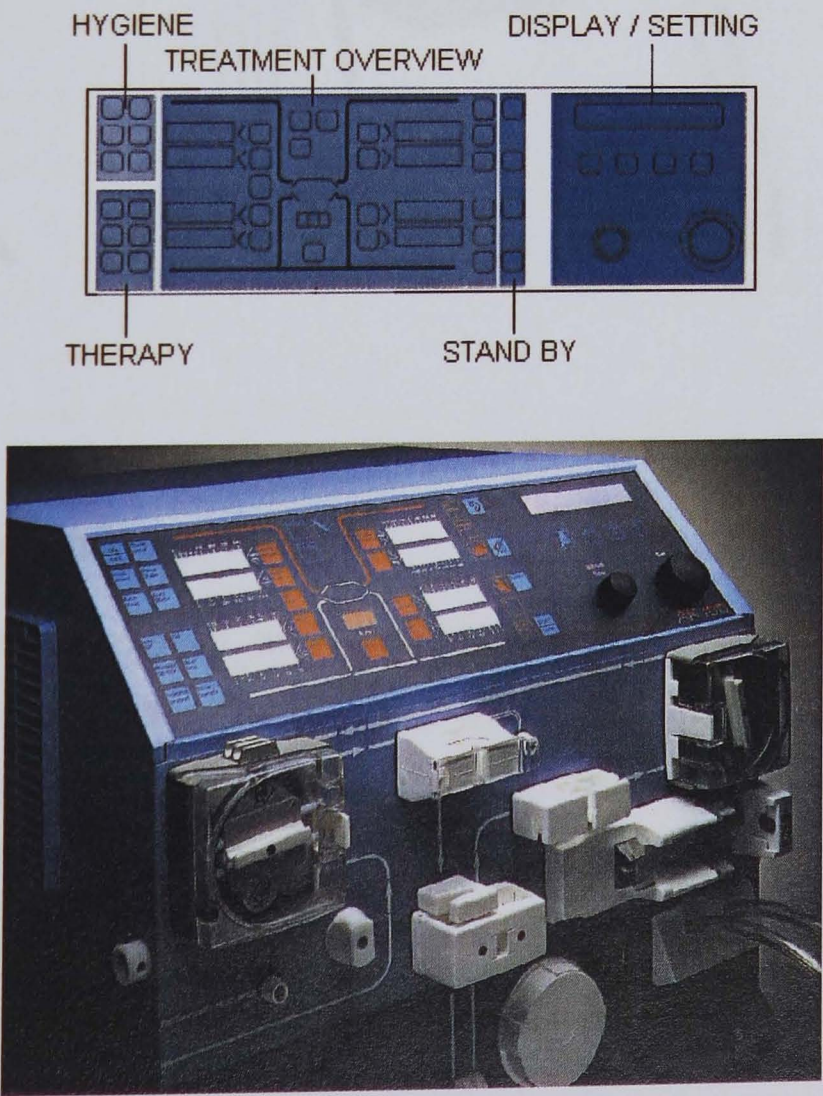
Gambro developed a direct access panel, because with the need to have so many menus down at the same time, if an alarm sounded, it was thought that people would be unsure how to go back.

Felding stated that,

It was a bad idea, of course it was our mistake, although I am sure it can be done. We want direct access whatever we are doing. If I am changing temperature or if I have zero pressure alarm, then I can always press the button and handle that alarm. We want to see what is happening so that is why there is more or less one button for each important parameter that can be adjusted.

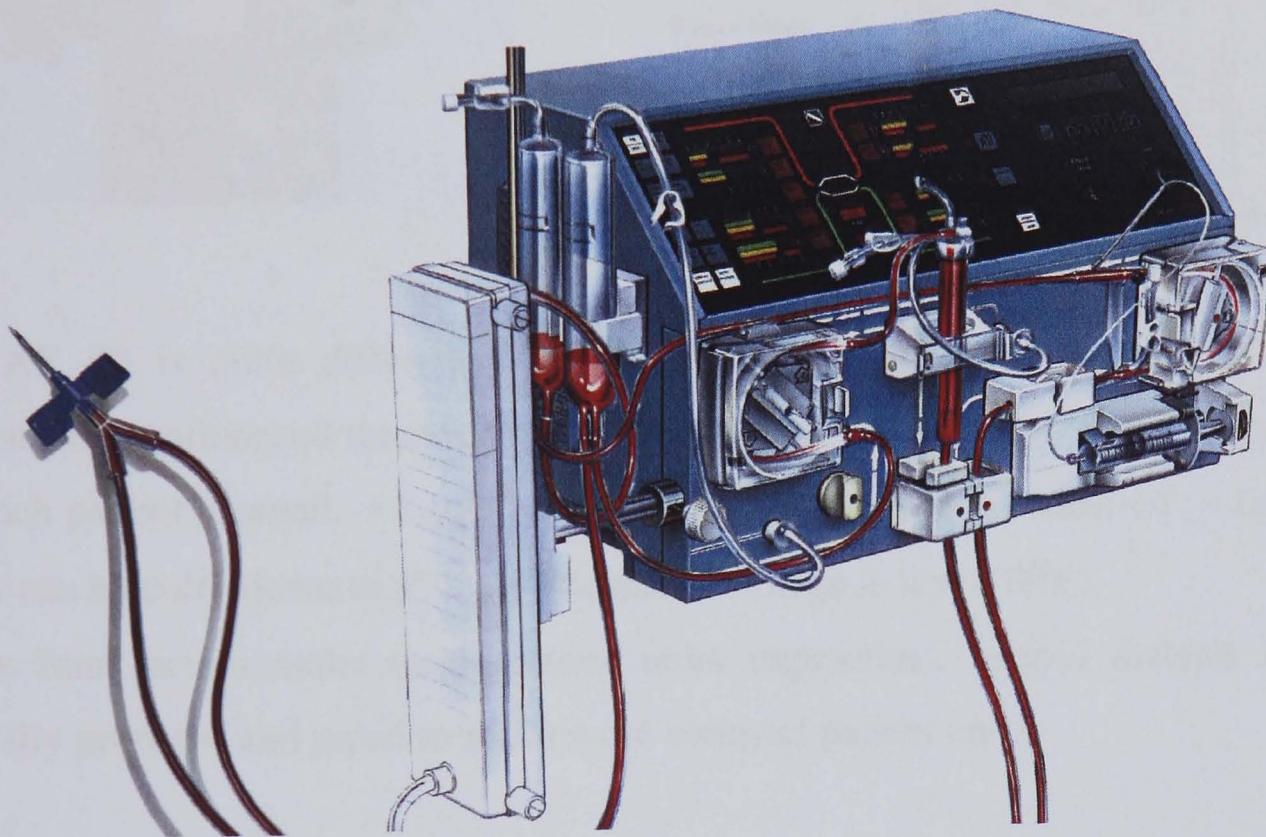
Therefore, Gambro decided to have a direct access panel. Whatever problem a user may have, the user can always push an actual button and so can handle an alarm situation.

Figure 10-4. Control panel of AK 100 (Source: More care in renal care, 1990)



While developing the AK 100 Gambro also began developing a relationship with TÜV Bayern (one of the important test houses in Germany). One of the reasons for this was to get the equipment 'MedGV' approved. Without this approval no equipment can be sold in Germany. The AK 100 was finished, and approved and became a huge success in all the Western European markets. It was, and to some extent still is, a state-of-the-art machine, fully equipped as a single-patient unit (Mols, 1995).

Figure 10-5. AK 100 single needle system (Source: A single stroke of genius, 1994)



10.6.3 AK 90

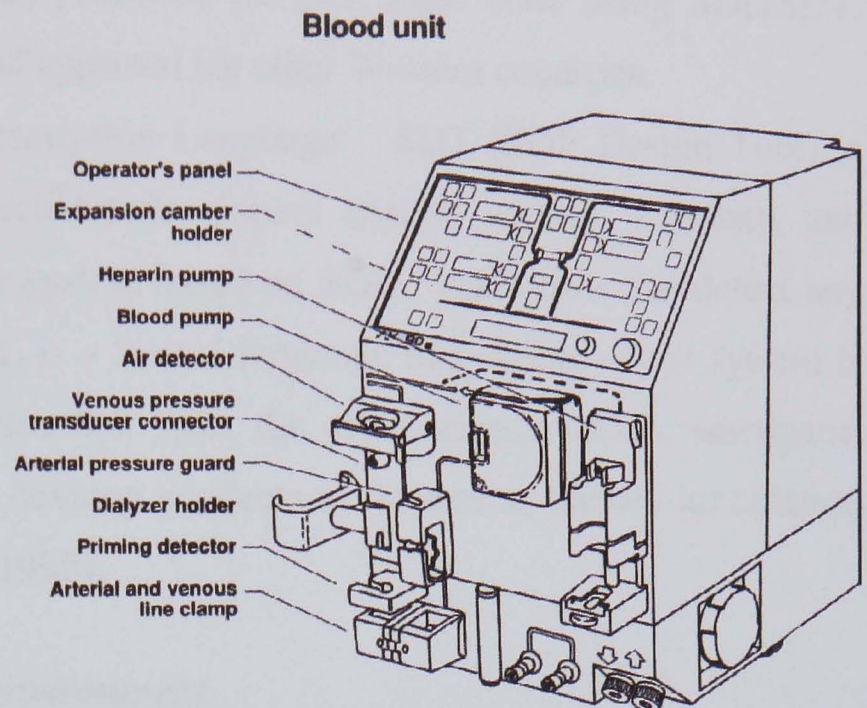
10.6.3.1 Reasons for modification

In the early nineties, European and American hospitals were gradually forced to economise on space and funds. The time had come to find something smaller, for basic treatment. The seemingly obvious solution was the AK 90, originally developed primarily for Japan. In Japan the number of dialysis patients is very high. This might be related to the fact that for some reason there are very few kidney transplantations (Felding, 1997).

Figure 10-6. AK 90 (Source: AK 90 Operator's Manual by Gambro, 1995)



Figure 10-7. AK 90 blood unit (Source: AK 90 Operator's Manual by Gambro, 1995)



The AK 90 is quite different from the AK 100, for several reasons. Four main requirements influenced the design of the AK 90 for use in Japan. • The space available for each patient is small. • Large amounts of dialysis liquid are required. • Japanese tap water can be cold (down to 4°C). • The mains voltage is low (100V).

These four factors make single-patient units impractical. Instead dialysis liquids are centrally prepared and piped to much more compact patient units.

According to Mols (1995),

Now this format is growing increasingly attractive to the Western medical world and, consequently, the AK 90 is an equally attractive concept.

At this point, however, it must be noted that Japanese safety regulations differ somewhat from European and American standards. To overcome these differences the protective system software had to be revised adapting Japanese safety to Western standards.

In a meeting with TUV, the German notified body, in early October 1993, Gambro presented the hardware and the way they proposed to solve the software revision.

The hardware was acceptable but the software methods were not. TUV required a new standard with encapsulated data, encapsulated code and possibilities to show the data flow. Gambro engineers went to work on the problem using their old, tried-and-true programming tools but failed to obtain acceptable results.

Mr Örndal was project leader at the Gambro design department, which started looking for another way out. At the beginning of February 1994, Gambro reported software development progress, in that they had produced all their logic code using SDL/SDT. Finally, TUV approval was obtained and approval for other Western countries.

SDL stands for 'Specification and Description Language'. SDT (SDL Design Tool), a development tool based on SDL which let developers analyse, design, simulate, and verify the functioning of any real-time system based on SDL. Such tools can detect any ambiguities in the design because SDL is a formal language that ensures each system is consistent. SDT is used in companies that span the telecommunications, aerospace, defence, and automotive industries to develop products as diverse as factory automation systems, and artificial kidneys (Mols, 1995).

10.6.4 Considerations for the home environment

There are many issues to developing products for the home environment. Anderson (1997) stated that there are two main aspects, cost and safety although safety cannot be compromised for cost. In order to keep the economics of production down, they have to bring down the costs of moulding. There are opportunities for new products but they may be less safe. He claimed

Just because we can do it doesn't mean we should do it. That's the key issue: again cost implication but safety aspect.

Felding (1997) added that in the home environment, colour and low noise are important when considering machine manufacture.

The ways people live are also factors for consideration in product development. Gambro introduced a dialysis therapy program, called 'Best use of Resources' which concerns home therapy, satellite therapy and hospital therapy (see Figure 10-8). For example, some home patients use dialysis machines in caravans, in their back gardens and others live in flats or nursing homes with small rooms.

The concept of the program is that the number of dialysis patients continues to increase. At the same time, health-care budgets are being cut and capacity is becoming limited. Under these conditions, quality care can not be provided for all. Anderson claimed that the program developed more cost-effective utilisation of available resources. The condition of the patient, the treatment required and the treatment costs are interrelated (see Figure 10-9).

Figure 10-8. Best use of resources (Source: Home Therapy by Gambro, 1997).



Home therapy is an option for new dialysis patients, and for those who are independent and capable. It means both reduced treatment cost and improved quality of life.

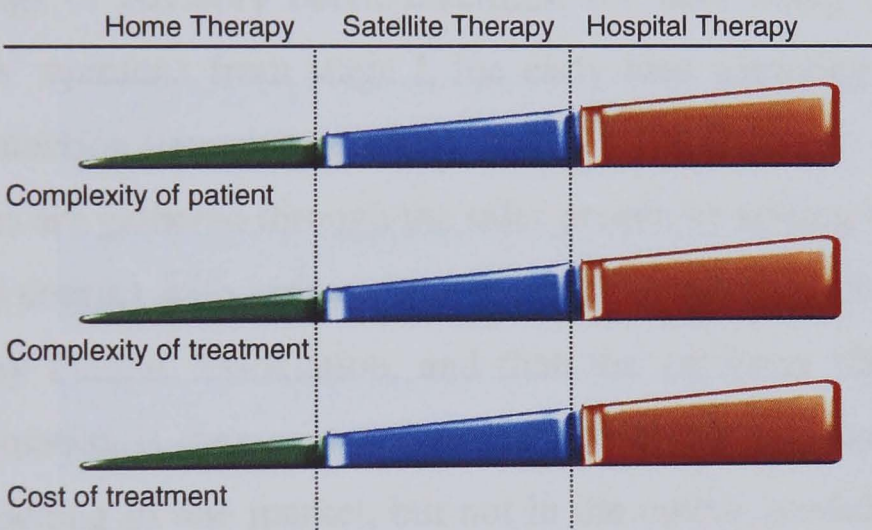


Satellite therapy means treatment of patients without serious comorbidities at facilities conveniently near their homes. Due to lower overheads and possibilities to reduce staffing, this option increases capacity and cuts the treatment cost.



Hospital therapy ensures individualisation for the growing number of high-risk patients. Their needs for specialised care can be accommodated with advanced, yet cost-effective treatment systems.

Figure 10-9. Concept of a dialysis therapy program (Source: Home Therapy by Gambro, 1997).



The dialysis machine is a very complicated machine, there are many parameters measured and patients have blood on the outside which can clot. Sometimes the machine stops because the BiCarbonate solution creates precipitation. This means that if a patient does not clean the machine, the pumps inside the film are suddenly blocked.

Anderson said

‘The technology should be used to make things simpler, not more complex. That is the key drive. But equally we want to know more and more about what is happening with the process. Dialysis is very empirical; we don’t know what it is. All we know is we take this factional thing away from patients. They will have 10-15-20 years depending on prognosis. What we know is if we do it this way we can get benefit to patients’.

10.7 Summary

Gambro is a multi-national firm, with headquarters located in Lund, Sweden. The company manufactures dialysis equipment under the three brand names, viz., Gambro, Hospal and Cobe. These have their own markets.

The Gambro emphasis is on software design rather than hardware or new design. The reason is that they want to keep their image in order to use previously existing components and equipment with ease of access such as blue boxed colour, control panels and blood line position. They developed a program to reach an increasing number of patients and also to fulfil the health-care budgets of various countries, which are being cut and where the limit of capacity is being reduced.

Gambro obtains users' opinions via the marketing department or sales department who work all over the world. The decisions to implement a new idea are made at marketing managers' meetings or advisory board meetings, the later being held 4 times a year. They obtain users' opinions from stage I, the early idea gathering stage and stage IV, after the main production (launch to market).

Customer opinions are gathered through the sales people by talking to hospital staff. The company also has contact with kidney patient associations of different countries such as the British Kidney Patient Association, and then the company obtains feedback from them. This information is then sent to Sweden for further development. Sometimes, if something is happening in one market, but not in the others, modifications can be made to a machine so that it can adapt to various countries' requirements. Gambro stress that they must make sure that all of these customers are happy in order to sell their machines.

As discussed, customer opinions are obtained at a number of stages and converted in a number of ways. It was also found that manufacturers have difficulties in converting feedback to the real product development.

Design and development happens in the engineering department. The company has hired industrial designers for design work on a few occasions but has not been satisfied with the results they produced. The company now uses industrial designers for certain purposes only, for example, for the appearance of a piece of equipment. Design and development is divided into 3 parts, mechanical (which includes boxes and pumps),

electronics (such as PC boards and electro circuits), and software.

In Gambro, design departments have strong production, engineering and technician involvement. The design department is responsible for the design and development of a new product and consists of electrical engineers, software engineers and mechanical engineers. When the company develop new products they start with a project group which has a project leader who is responsible for each new product development, various types of design engineers and an administrator. Sometimes when a new product is being tested they discuss design matters with the industrial designer. The international product manager is responsible for hiring industrial designers. But what industrial designers can do is very limited, for example, panel layout and changing colours.

The safety aspect is said to be important in most companies since the liability laws have been tightened and there are regulations and standards including ISO 9000, EN 46001, CE Mark, Dir 93/42/EEC, etc.

The reasons for product change are to stay in advance of competition, as can be seen with products such as the AK 100, and to comply with Safety regulations, as can be seen with the AK 90. In the case of the AK 100, the reason for the development was that the control panel was very complicated in appearance. It had many buttons over the machine, and many alarms. A new look for the control panel and ease of access to appeal to the customer were needed. As regards the AK 90, Japanese safety regulations differ somewhat from European and American standards. Furthermore, the previous version of the AK 90, did not meet European safety regulations and their requirements. The change to meet safety regulations became inevitable.

There is no haemo dialysis equipment specifically designed for the home environment. Moving equipment from hospital to home has been accomplished through training people to use it. Several factors which need to be taken into account for home haemo dialysis machines are cost, safety, colour, low noise, simplicity and feedback from users. The focus of marketing is the hospital and buyers. The move to home based equipment has placed the actual users another stage further away from the manufacturer.

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Chapter 11

Discussion, conclusions and
suggestions for future research

CHAPTER 11 DISCUSSION, CONCLUSIONS AND SUGGESTIONS FOR FUTURE RESEARCH

11.1 Introduction

The main purpose of this chapter is to assemble the findings of the surveys and case studies. Section 11.2 discusses the major findings of this research. Section 11.3 presents the general conclusions derived from the findings. Section 11.4 provides recommendations for the manufacturing industry and suggestions for future research.

The findings are presented in order to achieve the aims of this study. To remind readers, the detailed list of aims of this study is;

1. To produce a taxonomy of medical equipment leading to a practical definition of home-based health-care equipment.
2. To discover the benefits and deficiencies to the user of using home-based health-care equipment.
3. To identify deficiencies in the design process of home-based health-care equipment.
4. To add to the understanding of how design has an effect on new products.

The following sub-sections discuss the major findings in relation to the above aims. Before discussing the findings, a brief summary of the methods is given.

11.1.1. What was involved in the research carried out

1. Asking patients, as users, about their condition and the treatment and related equipment that was involved.

It was found that the patients were very willing to contribute to this enquiry; but their ability to contribute in a meaningful way to say how their equipment could be improved was very limited. Evidently this was because they were ill, and not so experienced in talking about how products perform. They were found to be even less able to say how such products might be improved by design. Also some patients had been using their equipment a long time and had long often about initial problems.

2. Asking medical staff about treatment, and equipment developed in hospitals, which is now tending to become home-based.

It was found that staff were interested in contributing their views to this study. It was evident that they knew a lot about the equipment and its use but in many cases, they failed to understand the problems of new patients, or how the equipment might be redesigned to perform better or become more widely available at a lower cost.

3. Asking manufactures about the equipment they produce and how they obtain information about what to incorporate in their product design.

It was found that manufacturers were willing to contribute to this study and discuss their product development methodology in relation to the system in which they find their products used. Clearly the manufacturers have to operate to economic business practices.

11.2 Discussion of the major findings of the study

11.2.1 Taxonomy of home-based health-care equipment

This study attempted to produce practical definitions of home-based health-care (HBHC) equipment (see Section 1.6, Definition and status of HBHC equipment). There are two aspects which have to be distinguished first, the equipment and second, the environment, in other words, the home. No clear dividing line was made between 'equipment' and other health adjuncts such as spectacles, inhalers and walking sticks etc. Neither was a precise dividing line made between family homes and other health-care environments such as old peoples' homes and hospitals.

However, it is useful to place equipment in different zones as follows.

Firstly, the equipment is used within a health-care environment, and is mainly located in a home environment which is variable. It can also be used in a general health-care environment such as a community or primary health-care environment. These locations are essentially variable whilst having nominal characteristics that offer useful opportunities for comparison.

Secondly, the equipment is operated by patients themselves, patients' families or health-care helpers rather than doctors or technicians.

Thirdly, the equipment must be operated by a power source such as mains electricity or

battery. This is part of the service provision within the environment – this also depends on the availability of suitable lighting, heating, clean water, drainage services etc.

Home-based health-care equipment (defined as equipment requiring a power source) is used in the ‘home’ by patients or helpers where ‘home’ can include various other caring environments. The important distinction from general medical equipment is that it is not used by doctors or technicians and therefore should be expected to require extra care in the design of special ‘user friendly’ features.

11.2.1.1 Types of HBHC equipment and categorisation

HBHC equipment is used in both the home-based health-care market and the medical market (see Figure 11-1). It was observed that the use of home-based health-care equipment is increasing with increasing market demand and advances in technology, allowing development of new products for both markets. Economic forces are clearly behind the movement of health-care into the home, away from costly hospital use.

HBHC equipment can be divided into 5 types (see Table 11-1 & Figure 11-2), namely, traditional HBHC equipment, newer HBHC equipment with market expansion, equipment used in both home and hospital, new opportunities for use in both home and hospital, and newer equipment used in both home and hospital. Figure 11-1 also includes equipment used only in hospitals, both traditional medical equipment used in the past and newer medical equipment with new markets within the medical market. In these last two areas, product models and product categorisation are not included since such information is beyond the scope of this present study.

The equipment included in the manufacturers survey has been categorised into 7 different groups (see Table 11-2), namely, respiratory equipment, hearing aid equipment, hygiene & transferring equipment, therapeutic equipment, dialysis equipment, monitoring equipment and ambulatory drug delivery equipment. The different product models included in the study can be divided into the different types of equipment (see Table 11-1).

Although this has categorised HBHC equipment in a way that is convenient for this study, it could be that different national health-care systems and financial systems may require different categorisations; but this is beyond the scope of the present study.

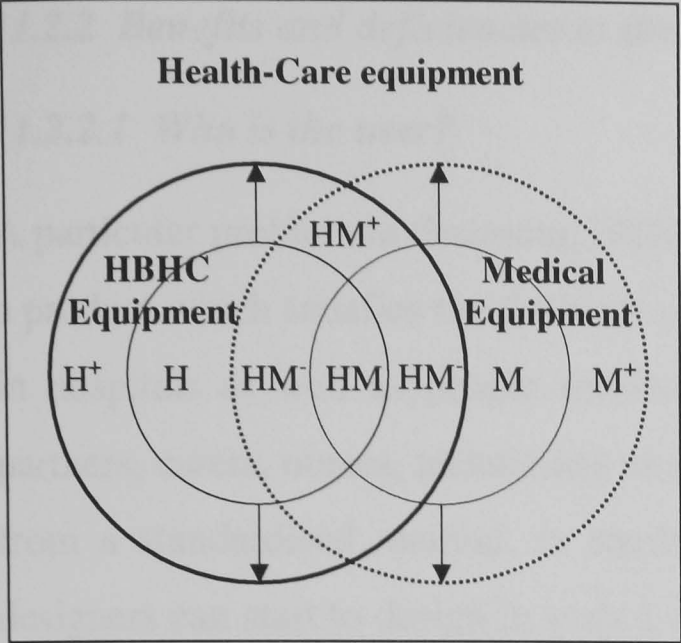


Figure 11-1. HBHC equipment and Medical equipment

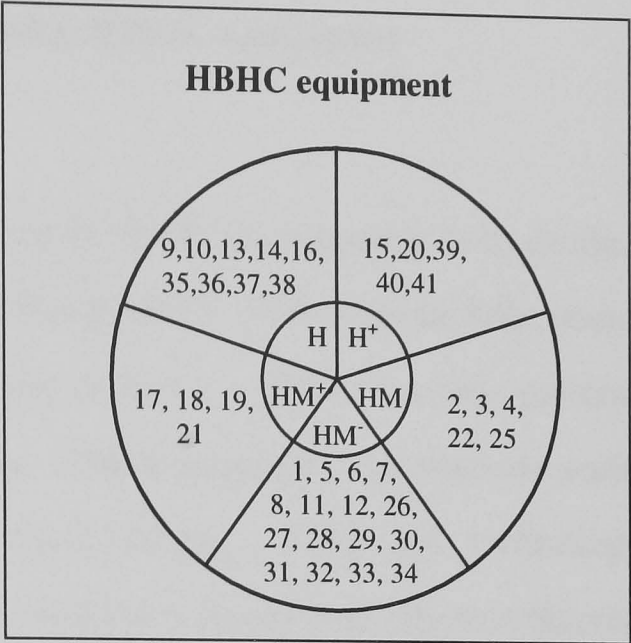


Figure 11-2. HBHC equipment types and their product models

Types	Types of equipment	Product models	Product categorisation
H	Traditional HBHC equipment	9,10,13,14,16, 35,36,37,38	E-I, E-III, E-VI
H ⁺	Newer HBHC equipment with market expansion	15,20,39, 40,41	E-III, E-IV, E-VII
HM	Equipment used in both home and hospital	2, 3, 4, 22, 25	E-I, E-V, E-VI
HM ⁻	New opportunities for use in both home and hospital	1, 5, 6, 7, 8, 11, 12, 26, 27, 28, 29, 30, 31, 32, 33, 34	E-I, E-III, E-VI
HM ⁺	Newer equipment used in both home and hospital	17, 18, 19, 21	E-IV, E-V
M	Traditional medical equipment used in the past		
M ⁺	Newer medical equipment with new markets within the medical market		

Table 11-1. Types of HBHC equipment and categorisation

Equipment types	Product model	Equipment types	Product model
E-I Respiratory equipment	1. Sonic 2000	E-V Dialysis equipment	21. HomeChoice
	2. AC2000		22. AK-10
	3. EconoNeb		23. AK 90
	4. World Traveller		24. AK 100
	5. Respicare	E-VI Monitoring equipment	25. G202
	6. Porta-Neb		26. Bio-Trac
	7. Freeway Lite		27. Baby Dopplex 3000
	8. Brompton PAC		28. Dinamap Plus
E-II Hearing aid equipment	9. AM510		29. Oxyshuttle 2
	10. Pro Series		30. DG Discovery
			31. TD50
			32. Medilog FD-3
E-III Hygiene & transferring equipment	11. Sara		33. Medilog 9000-II
	12. Sarita		34. DX Portable
	13. Eclipse	E-VI-2 Diabetes monitoring equipment	35. Accutrend
	14. Stratus		36. Precision
E-IV Therapeutic equipment	15. Cirrius		37. Companion 2 Card
	16. Pisces		38. Companion 2 Pen
	17. TENS	E-VII Ambulatory drug delivery equipment	39. Walkmed PCA
	18. Alpha Xcell		40. Walkmed 350
	19. AV Impulse		41. CADD-PCA
	20. HP 5224		

Table 11-2. HBHC categorisation and product models

11.2.2 Benefits and deficiencies to the user of using HBHC equipment

11.2.2.1 Who is the user?

A particular problem in designing HBHC equipment or medical equipment is to produce a product which satisfies the different needs of different users. The users include people in hospitals as well as people receiving treatment at home. These include patients, partners, carers, nurses, technicians or doctors, etc. The way people use products varies from a standardised method, in small but important details. With new technology, designers can start to design in such a way that a machine's actual performance delivery varies according to the needs of the user. For example, the user can have different displays, showing greater or lesser details of information, depending on the needs of who is looking at the screen, and what they need to know.

There are demanding user issues, which become key elements, that need to be addressed. Ramsden (1998) states that accurately identifying who the user is and what their requirements are, involves a lot more feedback to the user, because users want reassurance. A lot of healthcare equipment does not sufficiently give the desired level of reassurance or feedback to the different individuals concerned.

When people use equipment for a long time, they become used to it and problems are less noticeable. In the survey of home users, it was found that the majority of people had used their equipment for more than three years. This familiarity can cause problems if a new machine is needed, one which does not operate in exactly the same way as the previous one.

11.2.2.2 Benefits of using equipment at home

Many benefits of using HBHC equipment at home were identified through four different group surveys. These include convenience, saving time, saving travel and safety (see Table 11-3). A variety of answers was given for the most pleasing feature of the equipment (see Table 11-4).

Treatment type	Convenience	Saving time	Safety	Saving travel	Other
HHD	30.1%	25.7%	4.4%	29.4%	10.3%
HPD	36.6%	25.3%	8.5%	22.5%	7 %
HD	42.6%	29.6%	16.7%	9.3%	1.8%
HR	46.5%	13.9%	18.6%	16.3%	4.7%
Total	36.2%	24.7%	9.5%	22.4%	7.2%

- HHD: Home haemo dialysis
 - HPD: Home peritoneal dialysis
- HD: Home diabetes
 - HR: Home respiratory

Table 11-3. Benefits of using equipment at home

Treatment type	The most pleasing feature of the equipment	Percentage
HHD	Reliability	31.9%
	Saves their lives	14.9%
	Easy of use	19.1%
	Finishing the dialysis	6.4%
HPD	Time manage	33.3%
	Function	25.9%
	Easy to use	14.8%
	Display	14.8%
	Mobility	7.4%
HD	Reliability	16.6%
	Ease to use	16.6%
	Simplicity	11.1%
	Disposal	11.1%
HR	Portability	39.1%
	Relief	30.4%
	Reliability	13%
	Always at hand	13%
	Easy to use	13%

Table 11-4. The most pleasing features of the equipment

Other benefits and pleasing features were also identified (see Table 11-5). As the below table shows, one HHD patient said dialysis is pleasing but another one said there are no pleasing features. This means that people have psychologically different reactions to using the same equipment.

The use of equipment at home gives many benefits and pleasing features to patients. All equipment examined had good and bad points in terms of use, but if designers knew what users wanted and needed, the benefits and pleasing features of using the equipment could be optimised.

	Other benefits & pleasing features
HPD	More independent life style-10h/week
	Ability to lead a new normal daily life & being able to take it on holiday etc.
	Control over own treatment.
	Feeling better than I did with the other methods of dialysis i.e. Haemo dialysis & CAPD.
	Can use overnight
	Days are completely free
	Keeps me alive
HHD	Better life style
	Control of illness
	At home, it is psychologically better. You are not associating with 'sick' people
	There are no pleasing features, it is a necessary evil. It must be used to keep me alive!
	Dialysis is pleasing
	When I first trained on the C2 it was user friendly in that it is painted on the front with blue & red lines & arrows to indicate positions of venous & arterial lines. Alarm lights etc. are easy to understand & if it alarms it is a matter of systematically looking for the problem.
	Sensitivity
HD	The Cobe C2 is not computerised. Any adjustments can be started out by the operator.
	No pain
	Good result
	Easy to carry
HR	Can be connected to computer
	Do not have to go into hospital as often
	It helps to remove sterol congestion
	240 volt
	Lack of admissions

Table 11-5. Other benefits and pleasing features

11.2.2.3 Problems experienced by users

Deficiencies in HBHC equipment became apparent as a result of this research. This section assembles all the findings of problems experienced by users and produces a design checklist (criteria) for new HBHC equipment design. The study investigated a variety of products with different design features. As a result of this, it was anticipated and intended that some general guidelines for future design of HBHC equipment might be found.

Checklist (criteria) for new HBHC equipment design

Problems identified were categorised into 5 different factors; namely, usability, performance/ function, appearance, the user and the environment. Then, each general factor was expanded into more specific criteria (see Table 11-6), as a checklist of identified problems, based on appropriate descriptions given by interviewees.

Design Criteria			Identified problems (Check list)
User	Physical ability		Some patients have difficulties in using equipment because of their eyesight, impaired dexterity or disabilities.
	Patient activity		During the treatment, patients may need to have certain activities such as going to the toilet or doing something else rather than waiting until finishing their treatment.
	Psychological effect		Some equipment gives the impression that they are somebody unable to do anything
Usability	Access, installation & set up		The product has complicated installation or set up
	Control	Visibility	Difficult to read control panel
		Ergonomics	Difficult to use
		Operation	Lack of consideration of how and where to use
	Maintenance		After use, cleaning is difficult
	Training		Some equipment needs to have a long period of training
	Instructions to follow		Difficult to follow the instructions
Appearance	Lay-out (control)		Badly designed control panel produces errors
	Aesthetics / Finish		The appearance is not pleasant
	Size		Some equipment is too big to use
	Height		Several products are too low to use
	Weight		Some equipment is too heavy to carry
Performance / Function	Noise		During the treatment the machine produces a loud noise
	Safety		Some equipment is unsafe to use (sharp corners and wires). Lack of consideration if using with other equipment may produce safety problems.
	Robust / faulty		Some equipment has so many faults that even the manufacturer can not fix it.
	Mobility / portability		Some equipment can not be carried
	Adjustment		Difficult to adjust
	Time spent		Some treatment takes too much time.
	Storage		Lack of consideration of how and where to store
Environment	Water / electricity		Some equipment needs to be continuous to carry out treatment.
	Home assessment		Lack of home assessment results in an inability to use products. Some equipment can not be installed because ceilings can not take the weight.
	Using with others		Lack of consideration if using with other products and some products can only be used with their own make products.

Table 11-6. Checklist for new HBHC equipment design

Problems identified were between the user and the machine within the home environment. Figure 11-3 shows interaction of the 5 main criteria, namely, the user, usability, appearance performance / function and the environment. However, a better understanding of the interactions between each criteria is crucial in order to optimise future product design and development.

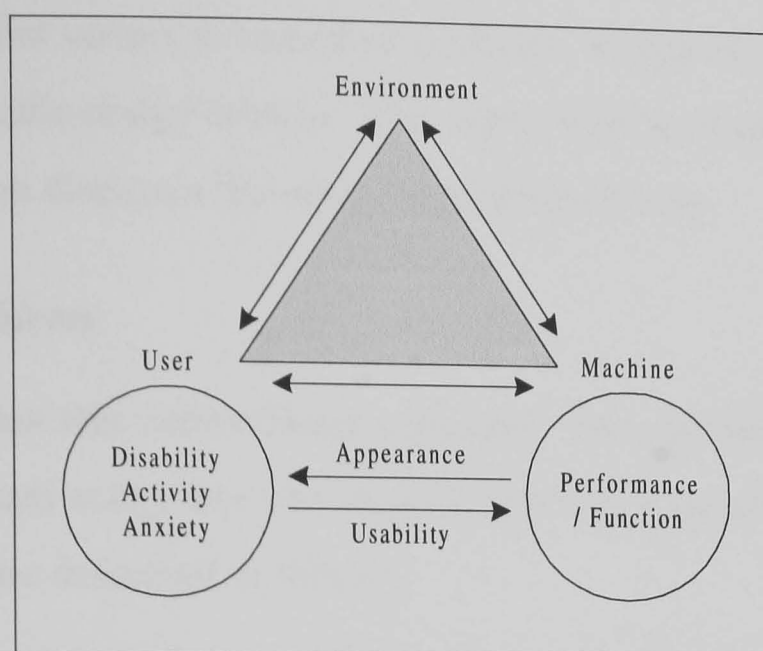


Figure 11-3. Interaction between user and machine within the home environment

Checklist of recommendations for improving the designing of HBHC equipment

The checklist of identified problems, based on interviewee answers (see Table 11-6), can be converted to produce a checklist of more precise design criteria and recommendations in order to help to optimise future product design and development.

1. User: Designers should consider more, the user's physical capability and limitations, user activity during the treatment and the psychological effect of using equipment during the treatment period.
2. Usability: Designers should consider ease of installation and set up, access, control and instructions, maintenance before and after use and, if training is required, whether this period can be reduced. Above all, ease of use is a key element.
3. Performance / function: Designers and engineers should solve problems relating to noise, durability, mobility, adjustment, safety and faults in mechanisms as well as aim to minimise the actual time of treatment.
4. Appearance: Designers should design the product with appropriate lay-out, aesthetics, size, height and weight.
5. The environment: Designers should observe where the product can be stored, if and how it can be carried, whether it can be used with other products, if the product needs a power or water supply, and if it needs special installation to mains services within the home environment. It is implied that designers need to have correct information about home assessment, such as where equipment can be installed.

Although, the checklist covers a variety of products, design of different products will involve different specific design criteria. This aspect will be further discussed in section 11.4. The next section discusses the other identified problems.

Other identified problems

There are other issues that interviewees suggested were problems. These are broad national problems, such as expense and limited/ insufficient supply of equipment. Other identified problems are described as follows;

Criteria	Identified problems (Check list)
Expense	The products are expensive compared with the quantity of products which the company produces.
National problems	Running out of hospital space and not having enough nurses to cope.
Restricted supply	Products only can be provided within certain age and conditions. Certain products can not be used by patients alone.

Table 11-7. Other identified problems

In renal units, identified national problems are that hospitals are running out of places and do not have enough nurses to cope, therefore, driving the system to change towards home health-care. In addition the machines are very expensive. This sometimes means that only patients with severe (acute) problems are treated in hospitals.

Anderson (1997) stated that there are problems with the restricted supply of equipment in the UK. For example, 12,000 dialysis machines are used in the home environment, but in France they have the same population with 22,000 home dialysis users. The reasons he gave are that in the UK, until 6-7 years ago people who were under 15 or older than 55 and people who were not married could not get dialysis machines because the machines generally needed to be operated with somebody's help.

11.2.3 Deficiencies in the design process for HBHC equipment

11.2.3.1 Absence of user input to the design process

To identify the design process used by manufacturers is a way of trying to understand when users' opinions are obtained and how these are converted to the actual design development. In fact, users' opinions were found to have a minimal place in design procedures. Time to market and regulatory pressures were considered more important.

Most of the interviewees, such as Bentely (1998), Hobday (1997) and Henderson (1997) claimed regulatory matters have an important impact on design procedures. There are regulations and standards including ISO 9000, EN 46001, CE Mark, Dir 93/42/EEC, etc. These require that medical products comply with a set of essential requirements relating to performance, health and safety. The result is a focus on the safety aspects of design and construction rather than on the user's perception of what is important.

Some of the deficiencies in HBHC equipment are the result of decisions taken during the design process. Not all the problems, however, are the result of 'bad' decisions. Some problems result from the fact that to survive, manufacturers have to sell their products to the people responsible for purchase decisions, who are rarely the ultimate users.

In the UK, the buyer would normally be an equipment budget holder, for the hospital or other medical community. Therefore, the actual end user will not usually be the purchaser or even be included in the purchase decisions. Some products can be bought privately, but this is a small proportion of UK transactions. The people who have most influence on the purchase of equipment are normally the consultants in charge of the units, so manufacturers have to target them rather than patients and their helpers (see Figure 11-4). In extreme cases, as claimed by Ramsden (1998), manufacturers tend to start with 'a lot of flashing lights' and things that go 'beep' to attract the doctors and then they need to remove them all for the people who actually use them.

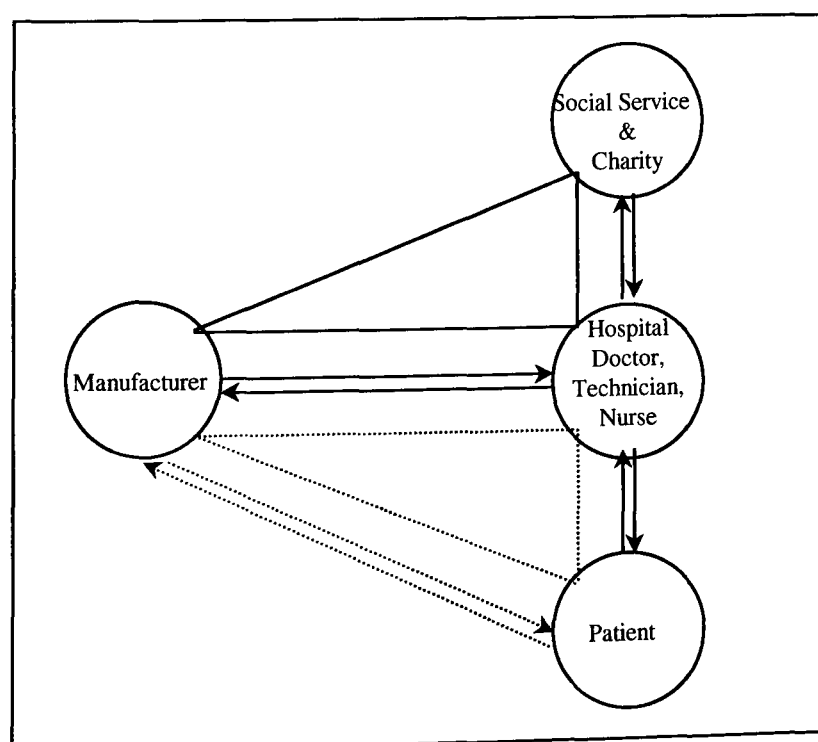


Figure 11-4. The purchasing process in hospitals

In the renal unit visited, purchase decisions are made by senior staff e.g. the senior nurse manager. However, Smith (1996) claimed that technicians who look after the equipment and go round the houses to maintain the equipment may also have some influence in these purchase decisions and such technician feedback was noted by manufacturers.

It was evident that medical staff in hospitals were considerably involved with the treatment specification and in the evaluation of product hardware performance.

All of the manufacturers claim qualitatively to have incorporated customers' opinions into the product change briefs. The majority of the manufacturers obtain customers' opinions via the marketing department or sales department. In questionnaires carried out for the manufacturers' survey, a total of 62 answers were given by 22 firms (see Table 11-8).

Source of customer opinions	Number	Source of customers opinions	Number
Customer enquires	18	Focus group	2
Sales department	18	Panel meetings	1
Questionnaires	8	Literature	1
Customer homes	8	Discussions with medical staff	1
Market research	5		

Table 11-8. Source of customer opinions

Manufacturers obtain customers' opinions from a number of stages and the design process was divided into four stages (see Table 11-9). They are stage I - the early idea gathering stage, stage II - development stage, stage III - pre-production stage and stage IV - after the main production (launch to market).

Manufacturers		Stage I	Stage II	Stage III	Stage IV
A & M Hearing Ltd.		○			○
Arjo Ltd.		○	○	○	○
Baxter Healthcare Ltd.		○	○		○
Clement Clarke International Ltd.		○			○
Drager Ltd.		○			○
Edale instruments		○			○
EMS Ltd.		○		○	○
Gambro		○			○
Gimson Stairlifts Ltd.		○		○	○
HNE Technology plc Group	Huntleigh Healthcare	○			○
	Huntleigh Kinetics	○	○	○	○
	Huntleigh Diagnostic	○			○
Medex Medical Ltd.		○			○
Medic-Aid Ltd.		○			○
Novamedix Ltd.		○			○
Oxford Instruments Ltd.		○			○

Table 11-9. Stages of obtaining customer opinions

It is significant to note that all the manufacturers interviewed obtained customers' opinions in stage I and IV, the early idea gathering stage and after the main production stage. The majority of manufacturers did not obtain customers' opinion in stage II and stage III. In fact, only two of the manufacturers interviewed, namely Arjo Ltd. and Huntleigh Healthcare, obtained customers' opinion at all four stages.

Gambro and Huntleigh Healthcare found that it was difficult to satisfy all their customers.

Felding (1997) said,

'If I speak to only one customer it might be a good idea for him but it will not be suitable for another person. That is sometimes treated as a problem, in that we need to make something that is both very universal and flexible. That is the challenge'.

According to Daugherty (1998), people in the health-care industry are actually saying what customers want or do not like but the company finds it very difficult to come up with a concept of what they would ideally like.

In fact, the user group or focus group is an ideal concept that the company would like to follow. But forming user or focus groups is very time consuming, and often people do not want to take the time out to be involved.

Huntleigh Healthcare does user studies or comfort trials of its products. For example, the evaluation team covers up various Huntleigh Healthcare's products and other companies' products with sheets. The testers move down three or four beds and rate the beds from the most comfortable to the most uncomfortable, etc. Generally 50% vote Huntleigh Healthcare's products as the most comfortable and 50% will say it is the most uncomfortable. So this shows that the perception of comfort is extremely subjective and very variable.

Generally, customers' opinions are obtained at a number of stages and converted to design criteria in a number of ways. It was also found that manufacturers have difficulties in converting feedback into real product development. A further problem is that, as stated in Section 11.2.2.1, customers and users are different people and have significantly different expectations.

Hamilton-Farrell (1998) believes that manufacturers may talk to one or two people and get an idea and say that 'We know what you want', but he believes they do not actually or sufficiently know what is wanted. Daughtery (1998) said,

A lot of the time we tend to do it (develop a product) on the belief that we understand what the market needs are. Our products are fairly simple, so once we have got some initial feedback and we have done a design specification we tend to try to stick with that design specification and we would push that down to almost a finished product.

The trouble is that their views may not be the same as other people's views so that makes it hard for manufacturers to satisfy everybody, and eventually they have to go ahead and build a piece of equipment on the basis of 'professional experiences' or 'professional misconceptions' (Ramsden, 1997).

It is recognised that more effective communication occurs now than previously, but it would be better to have more systematic communication between equipment manufacturers. If medical equipment manufacturers consulted more with the people who actually use the equipment, they would at least find out some simple factors very quickly (Hamilton-Farrell, 1998). It was evident that patient users were sometimes consulted, but the information produced from this was of low quality and of very limited use in evaluating existing products and even less use in developing new products.

Ramsden (1997) claimed that the problem with healthcare manufacturers is their conception or view of who the user is and who the customer is. They are very rarely the same person, and trying to get feedback from patients is considered to be very difficult by some companies. The manufacturers would normally approach the clinicians first to see if they had any problems using the equipment. Quite often the response might be that they have no problems, because if clinicians admit to having a problem using equipment then it could be perceived as a lack of skill on their part.

It was evident that manufacturers were not able to use patient generated information in product development and they preferred to use different systems which interpreted patients needs, which enabled product advancement. It was evident that their product advancement remained attached to and generally in the form of equipment originally used in hospitals.

It was evident that there is a lack of initiative in the design of treatment equipment specifically intended for home use, particularly when treating the less serious early stages of chronic medical conditions. It is possible that large numbers of people suffer early inconvenience or discomfort between General Practitioner consultation and the hospital consultation or diagnosis of need for hospital based treatment.

The results of feedback to Huntleigh Diagnostics showed that some of the devices on the market are quite complicated to set up and some of the features that could be set up, are consequently, not used. The devices which users ended up buying, are bought on the basis of experience of what was bought a previous time. Users prefer to use the same features all the time rather than the full range of features at different times, which might be available in a product with a more comprehensive product specification. So Huntleigh Diagnostics have tried to make products which are much more simple for users to set up and operate (Baily, 1997).

Trying to solve problems by modifications to existing products is arguably not as good as getting the design right in the first place. If manufacturers could get their specification and designs 'right' for HBHC equipment, they could plan for larger production, and benefit from efficient production tooling, and consequently, save money on the basis of the size of the production run. More and better products could be available for wider use by patients themselves, in their homes, at a significantly reduced cost.

11.2.3.2 Lack of industrial design

In the manufacturer survey, out of 56 people working in in-house design teams, only 5 were industrial designers (see Table 11-10). The majority of design departments are driven by strong production, engineering and technician involvement.

Professional make up	Number	Professional make up	Number
Industrial designer	5	Marketing	2
Technician	9	Clinical	1
Production	16	Quality	2
Engineer	16	Soft ware	2
Ergonomist	2	Hard ware	1

Table 11-10. Design department make-up

Although both the home-based health-care market and medical equipment market are expanding and opportunities for designers are growing, many medical equipment manufacturers do not employ an industrial designer because it could be said that they do not understand what this aspect of design can help to achieve. Industrial designers are involved mainly at the packaging stage. The problem is that industrial design is not seen, either by designers or manufacturers, as having a technical functional contribution to make to the development of health-care equipment, such as a consideration of user ergonomics. To many people in the industry, 'design' means 'engineering design'.

This study identified that there is not much differentiation in design between the hospital (medical) market and home-based health-care market. According to Daughtery (1997), the company tends to design the products with a view to the hospital market and the products naturally progress into the home care market, usually via the route of outpatient clinics, doctors, or the social services.

The manufacturer survey showed that 78% of products are used in both hospital and non hospital environment. It seems that manufacturers attempt to produce their product focused on clinical function and the mechanical point of view rather than a usability point of view.

Most of the manufacturer interviewees in this survey said new products are tested in a design quality department or engineering department. Those departments exist to make sure that the product is safe from a mechanical point of view. Any faults, size and sharp edges are also checked. Tests are carried out to see if it is possible to manufacture the product. The software is also tested to check that the product responds in the correct way (Felding, 1997).

The majority of hospital staff interviewees in the renal unit survey suggested strongly that there are not many problems with the machine itself, but there are more with the users. Problems are more likely through users not looking at what they are doing and missing out part of the sequence.

One reason for this is pointed out by Harrison (1997); normally an engineer/technician would design the machine and they would produce knobs and buttons on the front, the functions of which only an engineer/technician would understand. This suggests that if a machine were designed to be easier for the actual user to control, in home use operating errors would be reduced.

11.2.3.3 Other factors that emerged from the manufacturers

Other factors that emerged from studying the manufacturers are;

1. It was evident that the system administration was too influential in product buying and it did not have the ability to discriminate between existing products on the basis of user opinions or needs, etc. This appeared to interfere with new product development initiatives.
2. It was evident that products that have been developed at considerable cost tend to be copied quickly, and undersold by competitors. Some developments can be covered by design registration and patents; but it was also claimed that some competition is working outside international law in these respects.
3. It is known that complex high technology products are profitable to copy, thereby saving development costs. It is suggested that well designed, more basic products, are more difficult to compete with and these can be more profitable for the original manufacturer.

11.2.4 New product development and the role of design

Ease of use is a crucial issue in product design in general and especially in home-based health-care equipment design. This study found that many HBHC users experienced problems because of badly designed products which are used in the home and hospital environments; some products even required several months of training for their users. Many researchers including Langrish and Hwang (1996) claim that it is important to improve the usability of products and they emphasise user-oriented design.

Objects give messages about what they can be used for, in other words, what people perceive the new products can do. Section 5.3.6, Control systems for haemo dialysis machine operation, shows that different operations are afforded by different technologies. Hence, many HBHC users often fail to use some of the most powerful features of their equipment, features that some people often never know exist (Norman, 1993).

Many everyday products, including HBHC equipment, failed to meet at least one of 'Kripendorf's laws'. Norman (1986) argued that the designer should be responsible for the failure of the use of many ordinary products. However, the above explanation provides only part of the answer. Semantic theories could be applied to make the products more readily understandable, and easier and safer to use (Blaich, 1989).

Manufacturers seem more interested in their customers, i.e. the purchasers, rather than the users (Huang, 1996). This is particularly important when purchasers and users may be different people as is the case with equipment purchased by hospitals for use in the home.

Industrial designers can be involved with a variety of new product developments in the health-care area, from tooth brushes to invalid cars to a dialysis machine. There is evidence that planned design investment has a positive commercial benefit to the manufacturers (Pilditch 1987; Service et al., 1989; Potter et al. 1991; Bruce et al., 1997).

Nevertheless, the present research exercise found that manufacturers have serious misconceptions about design, and they do not yet sufficiently recognise the scope and value of industrial design. Although some manufacturers employ industrial designers, their role is mainly limited to influencing the shape and style of the product, choosing some materials and final packaging.

The case studies showed that new products are typically developed by an engineering design department or a production engineering department that creates an engineering function bias rather than a user centred product.

New product development and modifications are run as projects with a leader who is responsible for the project. Most product change is influenced by the company desire to be in advance of competition or to catch up with the market. In other words, most new product development is very much market driven. Typically, marketing is a 'trigger' for a design change (Bruce and Cooper, 1997)

Although some companies claim that anyone can suggest an idea for product change, this idealised situation does not happen often in practice. The majority of product developments are through the marketing department using a standard written form which outlines various categories, such as the benefits to the company in terms of increased business or a new opportunity, the benefit to the customers and the pitfalls and risks etc. (see Appendix 5. New product proposal).

It is recognised that design and marketing are interconnected. According to Bruce and Cooper (1997), frequently design and marketing share some of the same objectives, namely to develop the 'right product, for the right market, at the right price'. Cooper & Kleinschmidt (1986) claimed that marketing has a critical role in the product development process, particularly during the early stages.

A design department translates market specification or market requirements into a design specification with concepts and then develops these into the detailed design of appropriate products. All the companies in this study claimed to have featured users' opinions in their product change brief. It was claimed that customers' opinions are very important in order to develop a further direction for new product development.

However, such answers to the manufacturer questionnaires appear to contradict other evidence described in Sections 11.2.2.1 and 11.2.3.1. In reality, user opinions are largely ignored by companies. This is particularly true when users and customers are different people, and this represents a potentially valuable missed opportunity to design better products for the people who it is intended should use them.

Further, Norman (1988) claims that any problems users have are probably the design's fault, not that of users. He adds that a major problem is that often the purchaser is not the user.

The purchasing department orders equipment based upon such factors as price, personal relationships with the supplier, and perhaps reliability: usability is seldom considered... If you are a designer, help fight the battle for usability. If you are a user, then join your voice with those who cry for usable products. Write to manufacturers. Boycott unusable designs. Support good designs by purchasing them, even if it means going out of your way, even if it means spending a bit more. And voice your concerns to the stores that carry the products; manufacturers listen to their customers.

Many studies emphasise that distinctive good design of new products can create a desire in the consumer to purchase and this can contribute to the competitiveness and business success of the company (Bruce et al., 1997; Roy et al., 1993). The situation when customer (buyer) and user are different people provides an important variation. The customer may 'desire' features that are not wanted by the user and often fails to identify features that are important to the user. Designers need to know not only the target market and market requirement in general terms but also the actual user. In other words, the precise user requirements should be considered.

Home-based health-care equipment like many day-to-day products have problems in use. Careless application of technology tends to create problems for the user where functions have not been effectively communicated to the designer or built into the product by the designer. Surveys of washing machine users for example, show that many users have problems with the controls (Langrish and Huang, 1996). It is clear that if designers tend to design for the buyer rather than the actual user, then user problems might be anticipated.

11.3 Review of conclusions

This study has approached a complex area for investigation. It has opened doors to a subject that is important for improving the quality of life for people who are suffering medical conditions and undergoing hospital treatments that could possibly be better treated at home. However, this study clearly indicates that there are various problems that would need to be addressed and overcome before these problems can happen.

Equipment appears to be too complex and expensive. The health-care service is hospital centred rather than home-based. Specification and buying of equipment is not user controlled. Manufacturing is too dependent on hospital budget availability and institutional buying, as regards hospital equipment for treatment of acute conditions (see Figure 11-5, situation A).

As regards existing home use of hospital equipment for more complex home treatment of chronic condition or recovery conditions etc. (see Figure 11-5, Situation B), manufacturing specifications are over influenced by medical needs rather than the need to produce less complicated products that work very effectively, that are significantly less expensive to buy and are produced on a more economic production plan, for example, in appropriate quantities, with better tooling, more efficient production runs etc. to satisfy Figure 11-5, Situation C.

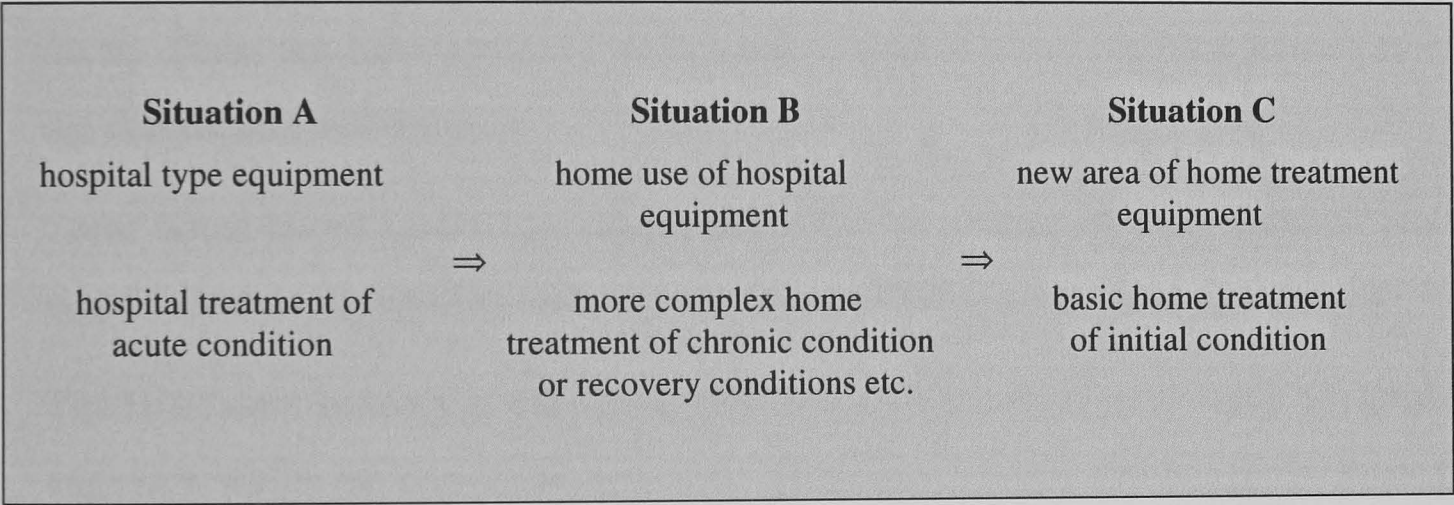


Figure 11-5. Use of equipment in different situations

In the near future for new area of home treatment equipment for basic home treatment of initial condition (see Figure 11-5, Situation C), it is thought that basic uncomplicated equipment could be designed and manufactured to treat large numbers of patients in the early stages of chronic illness, to stabilise their conditions and perhaps delay some deterioration towards more serious or acute conditions, which often involve full hospital service. This situation could consequently, reduce the need for the use of expensive hospital sourced equipment in the patients' home.

The conclusions made in the earlier parts of this chapter are now summarised as follows.

1. The home-based health-care market is growing with market demand and advances in technology allowing development of new products for the HBHC market. Economic forces, namely, heavy financial pressure restricting hospital activities, are clearly behind the trend of movement of health-care into the home.
2. Equipment was categorised into 7 types, - respiratory, hearing aids, hygiene & transferring, therapeutics, dialysis, monitoring and ambulatory drug delivery equipment.
3. The use of equipment at home offers many significant benefits to patients. These include convenience, saving time, saving travel, safety, etc.
4. A particular problem in designing HBHC equipment or medical equipment is producing a product which properly accommodates the different needs of different users. From the users' point of view, some problems were identified relating to set-up, control and maintenance.
5. Some home-based health-care equipment could be redesigned with domestic use in mind. This could improve usability and decrease the time required for training.
6. The healthcare industry is very traditional, most of the equipment being designed by engineers within the companies involved. There are still misunderstandings about the role of industrial design. To many people in the industry, 'design' means 'engineering design' and not design for people.
7. Regulatory matters have an important impact on design procedures. The result is a focus on the safety aspects of design and construction rather than the users' point of view.
8. All the companies claimed to have featured users' opinions in some way in their product change brief. It was claimed that customers' opinions are very important in order to develop a further direction for new product development. In reality, user opinions were found to have been largely ignored by companies. This was particularly true when users and customers (buyers) are different.

11.4 Recommendations and suggestions

11.4.1 Recommendations for the manufacturing industry

This section provides suggestions on how manufacturers may use these research findings about design to influence their current practices. There are many issues which need to be taken into account in making decisions about manufacturing new products.

Manufacturers have to operate to sound economic business practices. Part of a company's budget may be used to fund research design and development to create improved or innovative designs. Each manufacturer may know, to some extent, how to design their new products. But this research indicates that there are difficulties and weaknesses in the design process for manufacturers. Some manufacturers may not even realise the importance of design.

Manufacturers are trying to solve real market needs. One answer might be user centred design where ease of use and user needs drive the product. Especially, home-based health-care equipment should be designed to meet the users' real requirements. This could help towards solving the problem which lies with the way products are designed. Many product development teams emphasise technology and consult each other rather than the user, who does not have much technical background. Consulting users more could provide valuable information for improved design.

The design process should involve sensitive feedback from patients who use the equipment to modify and influence the next generation of product design. Because most patients are not good at explaining what is good or bad, the use of an individual who can understand and interpret what they need, in design terms, should minimise this problem, for example, with the use of appropriate industrial design and researcher.

It may be a good idea to get further ideas for improved design using consultants, medical surgeons, technicians, nurses, patients, etc., to improve manufacturers' products. But manufacturers need to establish the difference between home treatment and advanced hospital treatment equipment specifications. Perhaps home treatment can be fixed at a good base standard for a period of years - enabling equipment design and

production to benefit from tooling investment and economies of scale involved with greater production quantities of better, more reliable, easier to use, more pleasing equipment, etc.

State of the art treatment should be specified for home use and standardised for a reasonable period of time. This would enable the product to benefit from economies of scale in large production quantities. It would enable the product manual to be perfected and standardised using media methods that do not make excessive demands on hospital staff.

There may be good design development opportunities to contribute to health and rehabilitation in areas such as cardiac testing, hospital physics department, rehab after heart attack, etc. This could lead to products for treating the early stages in conditions before they are serious enough to be regarded as chronic or acute which after appropriate training can be trusted to home treatments.

A new market 'Think Tank' could be set up to identify trends, economic forces, education - in relation to home based health care equipment. New treatments at home, that avoid or minimise more serious and costly hospital treatment could be investigated.

Opportunities could be provided to use industrial designers with appropriate interests and experience to co-ordinate or at least contribute to such policies influencing 'Think Tank' initiatives. These changes in policy naturally involve risk but risk can be minimised through providing unexplored opportunities to maximise production and profits whilst satisfying the local needs of patient comfort and national economic needs to reduce pressure on hospital services.

It is very important to get a sound direction for any future new product development. It is hoped that manufacturers may find useful the findings and suggestions from this research.

11.4.2 Suggestions for future research

The scope for future research into the home-based health-care equipment and related areas is considerable. There are areas of research which this study has barely touched upon, but some suggestions for future research have been generated and are outlined as follows: -

11.4.2.1 Research on the users

This research initiated study of the problems experienced by users and attempted to produce a design checklist (criteria) for new HBHC equipment design. In this way, it was hoped that some general guidelines for the design of HBHC equipment might be found. However, much more research into a greater variety of products involving different design criteria for the different user groups would be required to produce a meaningful picture of the different design criteria for different products. These criteria need continual testing, examining, and modification so that accurate theoretical models might be developed and evaluated.

It was identified that users are continuing to have problems with their products, involving for example, control, set-up, maintenance, etc., even accepting that there have been improvements in design relating to ease of use. Further, user studies for ease of use might give more benefit to the user as well as to the general systematic procedures for designing more effective new products.

11.4.2.2 Research on manufacturers

The study identified that the importance of industrial design is functionally ignored by manufacturers, since they have misconceptions about the scope and value of good design. Therefore, the benefits of using industrial designers more effectively needs to be further examined.

From a design and development perspective, it would be interesting to ascertain the level of involvement of industrial designers in developing strategic product development decisions and carrying out participant observational research in this area.

This study looked at the home-based health-care industry in some depth within the scope of the resources available. The findings of this study may apply to other areas of industry which may gain a general conception of the importance of design. Problems with the use of products are not confined to the health-care market. Specific and general areas of concern would surely benefit from considerably more systematic research in the future.

11.4.2.2 Separation of users from customers

Some of the difficulties found with HBHC resulted from the fact that the people who make the decision to purchase are different from the people who use the equipment. It would be interesting to identify other examples of this phenomenon.

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Appendices

Appendix 1. Protocol A1

Appendix 2. Information for users A5

Appendix 3. An example of good practice permission A6

Appendix 4. Medical devices classification A7

Appendix 5. New product proposal A9

Appendix 1. Protocol

PROTOCOL

1. Title:

An exploratory study of users' reactions to home-based health-care equipment.

2. Aims:

- 1) To identify problems experienced by users of home-based health-care equipment.
- 2) In particular to identify problems associated with control mechanisms.

3. Wider Study:

This small exploratory study is part of a larger study looking at the role of industrial design in producing better control mechanisms for a wide range of consumer products. The focus of this larger study is product semantics.

4. Product Semantics:

In its application to control system requirements, product semantics is concerned with the way in which products can be designed to inform the user how to use them. It can be distinguished from;

- 1) Engineering which is concerned with the primary technical functions of the equipment, inner workings, reliability and safety of products.
- 2) Ergonomics which is concerned with the interface between product and user at the mechanical level. In the past, ergonomists have looked at such factors as the diameters of 'turn' controls and the amount of physical resistance required in 'push' controls. By contrast, product semantics looks at the product-user interface at the mental level.

Modern products have become more sophisticated and technically advanced but not always as simple to use as they need to be. In video-recorders, programming has become a joke. One study even showed users having problems with modern pocket torches (Huang, 1996). Three reasons for these problems have been identified;

- 1) In the 'old days' a lever said 'pull me'; a wheel said 'turn me'; a steam boiler had to be its characteristic shape, etc. However, with the growth of electronic 'black box' systems where works are inside, the old visual clues have become lost (Lin, 1996).
- 2) The trend of thermoplastics replacing metal and wood has created problems. For example, old metal torches with screw threads pressed into the metal had an outward visible sign that the user could unscrew the end to replace the battery. Modern

plastic torches with clever snap-fit connections rarely contain such visual clues (Huang, 1996).

- 3) The reluctance of many factories to employ industrial designers trained in this aspect of design. The modern pressure on consumer products is design for purchase rather than design for use (Huang, 1996).

It is hoped to extend existing studies of consumer products into the area of home-based health-care equipment.

5. Home-based health-care equipment.

The home health-care industry has grown rapidly in the last decade, driven both by technological advances and demands as well as by pressure of under financing of hospital services. Cockerill(1992) estimates that the world market has more than doubled in the last six years. It is claimed (Williams, S. & Williams, J., 1988) that in the USA, from 1978 to 1986 the number of hospital-based home health-care agencies more than doubled to over 1,000. During the same period, the number of independent home health-care agencies grew by over 80%. As regards Germany, Gerdemann(1992) states that in 1986 the health insurance funds spent 160.3 million DM (£ 55 million) on home care and in 1990 1,046 million DM (£359 million). This is an increase of 553 per cent in only 4 years.

Several factors are given for the shift to home care by many observers such as Owen, Selinger, Banta, Marks and Stocking. Stocking lists the following factors as the main reasons for the shift to home care.

1. There is the improvement of the home environment - telephone, refrigerators, electricity and good sanitation all make home care more feasible.
2. There is patients' dislike of hospitals, though patients will by no means always prefer to be at home. If they are gravely ill, alone and frightened, they may well prefer to be in a hospital. Overall, though, with adequate support most people would prefer to be at home.
3. Hospitalisation itself can be psychologically damaging, particularly to children and elderly people and, of course, the risks of infection are significant in hospitals.
4. Two most significant forces towards home care have been changes in the population and financial constraints, and these are inter-related.
5. Acute care at home has, therefore, been seen as a cheaper means of providing treatment. However, there are concerns about this. Firstly, although the costs of home treatment may be less there may be no cost savings unless the level of care in hospitals is correspondingly reduced; on the other hand, the hospital may be redirected to treat more patients needing more intensive care. Secondly, cost savings may be achieved only at the expense of families and friends. The burden on carers should not be underestimated, and there are worries that the effects on carers are being ignored.

Above all, economic forces are clearly behind the movement of acute care into the home in all countries. However, different national financial systems may make it easier or harder to support home care or to make savings in acute hospital care.

The most significant issue is that changes in technology including medical advances have made home-care more feasible, and manufacturers are developing streamlined, tamper-proof equipment intended specifically for the home care market.

There are, however, difficulties in this trend, some of which may be associated with problems in using the equipment. In some cases, as much as three months' training is required before home users are considered competent. In other cases, equipment that could technically be used at home is not considered appropriate because of complexity or the risk of 'doing the wrong thing'. There would, therefore, be considerable gains if equipment user demands could be made easier and safer. The proposed study is a first step in this direction, consisting simply of asking users if they have any operational problems with the equipment they use.

6. Method

1) Questionnaire

The enclosed questionnaire is designed to address users of home-based health-care equipment. (N. B. - users are not necessarily the same people as receivers of health-care) Although the main focus of the study is control interface, this is not intended to be obvious from the questionnaire. This is to avoid the well known problem in questionnaires of 'leading', sometimes described as 'putting ideas into peoples heads'.

This is an initial exploratory study and no detailed statistical analysis is intended. At this stage, it is sufficient to find out if people do actually experience problems in using equipment, and where these problems tend to originate.

2) Collaboration

2-1) The Renal Unit at Leicester General Hospital has 200 patients requiring haemo dialysis of whom 30 receive home-based treatment. In this case, 30 patients have received 3 months' training in the use of their equipment and 15 patients with APD (Automated Peritoneal Dialysis) machines.

If the 'user friendliness' of the design of the haemo dialysis equipment could be improved, there could be at least two benefits a) more patients could receive home-based treatment and b) the training period might effectively be reduced.

Ms. Toni Smith of the Department of Nephrology is prepared to support the investigation.

2-2) Dr. A. C. Burden of the Department of General Medicine and Diabetes at Leicester General Hospital is prepared to support an investigation of users of home diagnostic equipment such as the 'pen' glucose sensor.

2-3) Other departments at Leicester General Hospital may be prepared to become involved. One of the problems of organising hospital support for home-based

health-care equipment is that, in some areas, several alternative forms of commercial equipment exist and there is no equivalent of a 'Which' report to recommend the 'best buy'.

- 2-4) The collaboration with Ms. Marie Hamilton of the Renal Unit of Queen Elizabeth Hospital in Birmingham and Mr. D. D. Vara of the Respiratory Physiology Unit of the Glenfield Hospital are also planned. Separate applications are being made to the Birmingham Health Authority Ethics Committee and Leicestershire Health Authority Ethics Committee.
- 2-5) Equipment manufacturers. Unfortunately, most of the manufacturers of home-based health-care equipment used in this country are German or American. However, there are UK based manufacturers, such as MediSense, who would be interested in the study.

7. Summary

Approval is requested from the Ethics Committee for a questionnaire to be administered to patients and associated users of home-based health-care equipment, currently known to staff of Leicester General Hospital.

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Appendix 2. Information for Users

INFORMATION FOR USERS

Dear Sir/Madam,

As a product designer and a postgraduate researcher at De Montfort University, I am investigating the subject of technical medical treatment in the home.

I am particularly interested in home-based health-care equipment that has been designed for that purpose and I would like to know your feelings about any equipment that you have used.

Many health care products were designed more than ten years ago, especially for home use. My research is planned to make sure that the necessary requirements are built into the equipment to make it good to use at the design stage, therefore, to be of benefit to the user.

As an established medical equipment user, your opinions, will be much valued and it is hoped that benefit will be gained through the design of better equipment in the future. It would be very helpful to my research if you could complete my questionnaire below.

Sang-Young Lee,
Research Fellow

Ref : Q400

Appendix 3. Example of Good Practice Permission



NURSING & ALLIED PROFESSIONS RESEARCH ETHICS COMMITTEE

THE JOHN RADCLIFFE

Manor House
Headley Way, Headington
Oxford OX3 9DZ

Tel: 01865 222692/222547

Fax: 01865 222699

Our Ref. LC/CEB/N97.032

6th August 1997

Mr Sang-Young Lee
School of Design & Manufacture
De Montfort University
The Gateway
Leicester, LE1 9BH

Dear Mr Lee,

re: NAPREC 97. An Exploratory Study of Users' Reactions to Home-based Health-care Equipment.

Thank you for your letter of the 29th July 1997 regarding your study.

I am happy to grant you ethical approval for this study subject to one amendment. You state in point 4 of your letter that you will add the sentence: "Your reply will be treated in confidence and only the overall findings will be made public". I am concerned that this is an ambiguous statement, and would prefer that you make it clear that although the findings will be made public, individuals will not be named, and that any data collected will be confidential.

Thank you for granting us permission to use your information letter as an example of good practice.

Best wishes for your forthcoming study.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Lindsey Coombes', written over a horizontal line.

Mr Lindsey Coombes
Chairperson
Nursing and Allied Professions Research Ethics Committee

Chairperson: Mr Lindsey Coombes

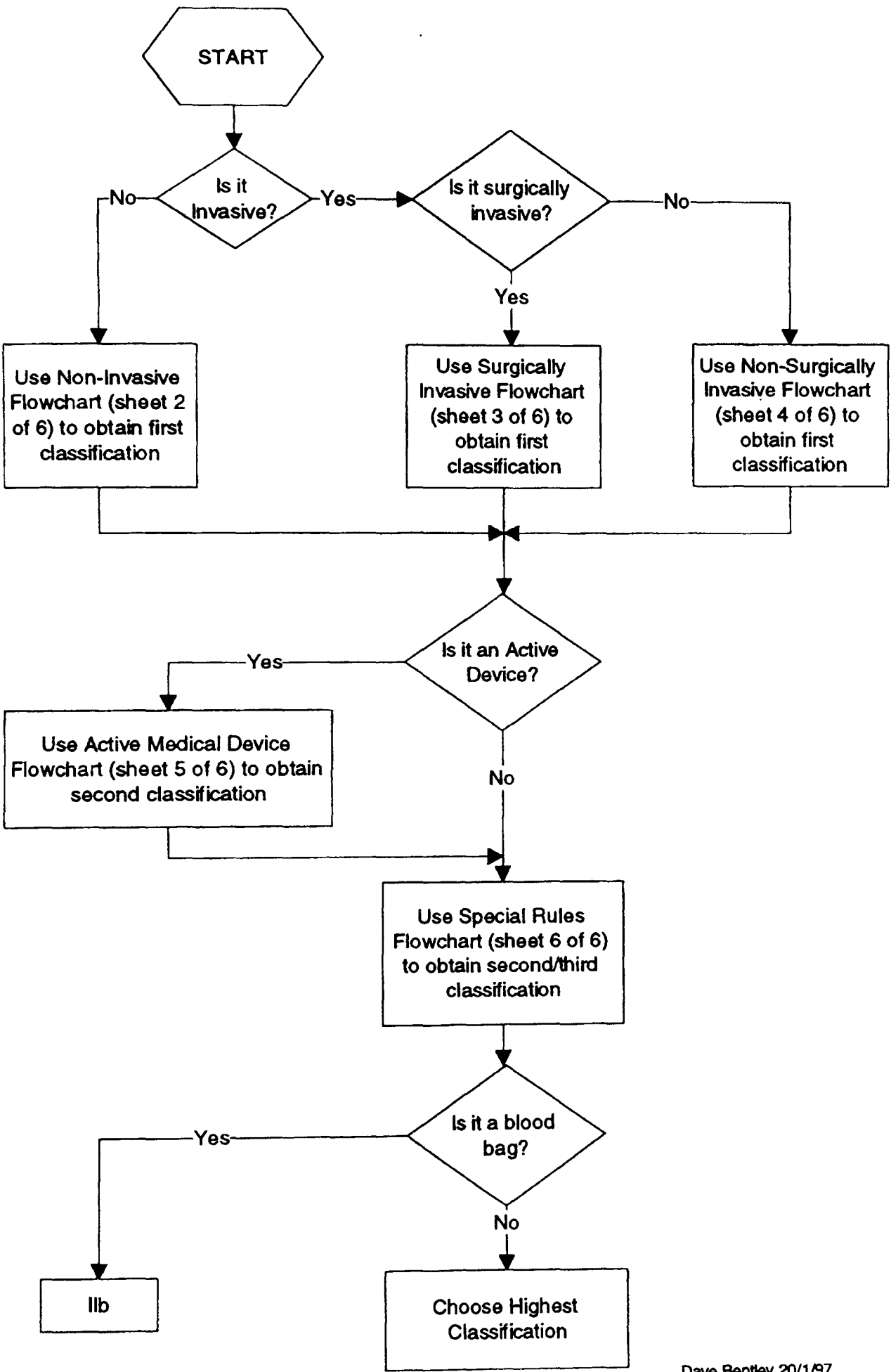
The Oxford Radcliffe NHS Trust is now managing the administrative support for the
Research Ethics Committees under a Service Level Agreement to Oxfordshire Health Authority

*The Oxford Radcliffe Hospital
A National Health Service Trust*

Appendix 4. Medical Devices Classification

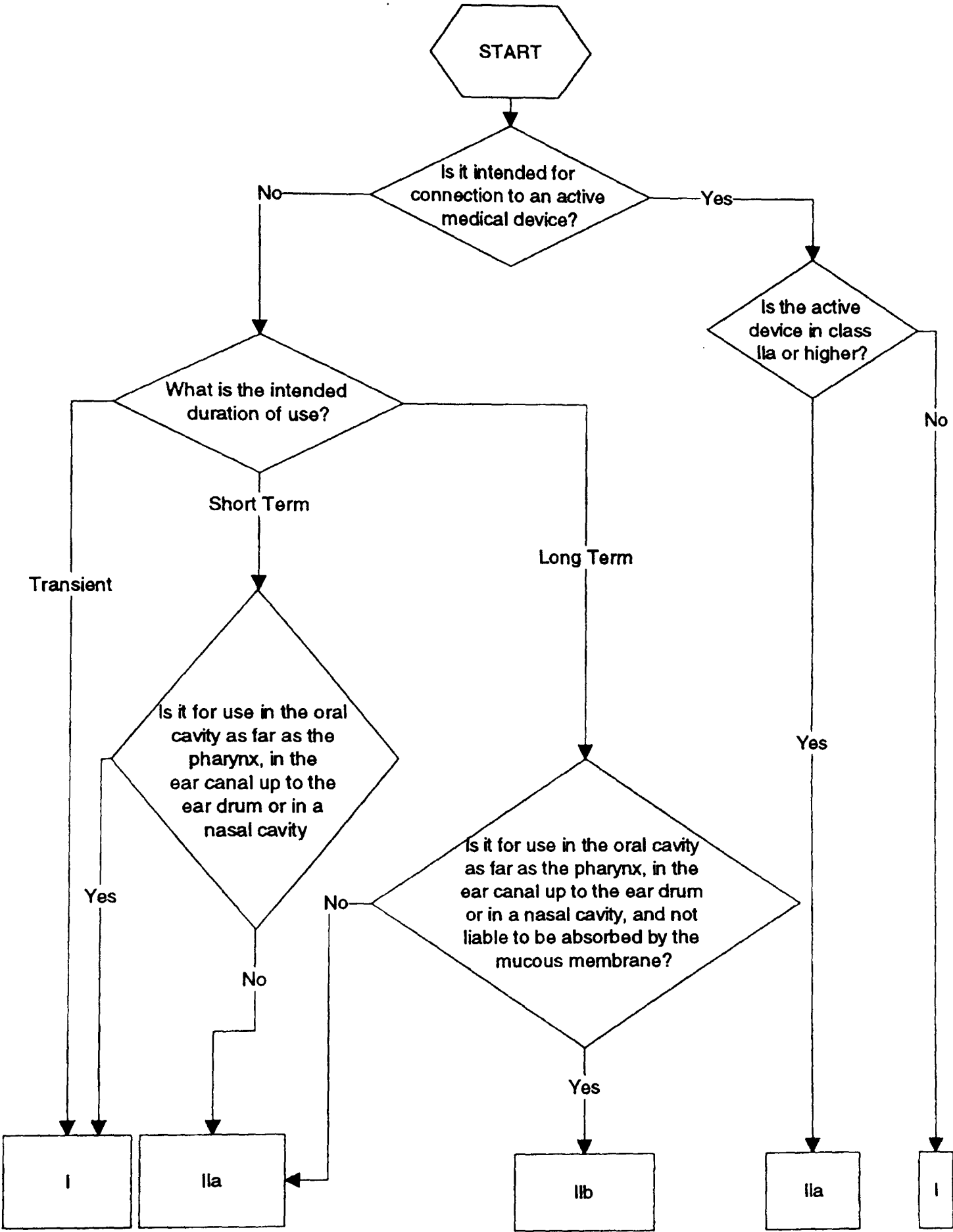


MEDICAL DEVICES CLASSIFICATION MASTER FLOWCHART





MEDICAL DEVICES CLASSIFICATION
NON SURGICALLY INVASIVE DEVICES



Appendix 5. New Product Proposal

NEW PRODUCT PROPOSAL

IF RED

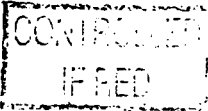
Section 1

(To be completed by Originator before submission to Technical Manager)



Product	<input type="checkbox"/>	Service	<input type="checkbox"/>
PAC	<input type="checkbox"/>	IC/DVT	<input type="checkbox"/>
Country of Sale -			
Idea Description -			
What			
For Whom			
Features			
Rank On Scale 1 to 5			
(1= nice to have, 5= must have)			
Rationale -			
Why Needed			
When Needed			
Customer Benefits			
Huntleigh Benefits			
Comments/Supporting Information -			
Attachments -			

Initiator:	Issue No. :	Date:
Technical Manager:		Received:



NEW PRODUCT PROPOSAL

Section 2
(To be completed by Technical Manager)



Technical Managers Assessment of Proposal :	
Acceptable <input type="checkbox"/>	Re-define/Re-submit <input type="checkbox"/>
Comments:	
PRG's Collective Assessment of the Proposal :	
Reviewed against	
1) Existing Plans/ Products/Services	
2) Market Demand	
3) ROI verse Risks	
4) Marketing Tactical Value	
1. Commit To Initial Assessment Stage	<input type="checkbox"/>
2. Kill Proposal	<input type="checkbox"/>
3. Put Proposal On Hold	<input type="checkbox"/>
4. Approve As A Fast Track Project	<input type="checkbox"/>
Initial Assessment Commitment :	
PA Number -	Project Title -
Team Leader - Team Members -	
Defined Scope of Assessment - What	
Constraints	
Timescale -	
Budget -	
Priority -	
Fast Track Commitment :	
HM Number -	Project Title -
Project Manager - Team Members -	
Circulation -	
PRG:	Managing Director Quality Assurance Manager UK Sales Director International Marketing Mgr Programme Manager
Group:	Chairman Technical Director
Originator:	Manufacturing Manager PAC Technical Mgr IC Technical Mgr Marketing Director Clinical Director Assessment/Project Team :

Technical Manager:	Date:	Issue No.:
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